Reserved procedures in Dutch health care: practice, policies and perspectives of physicians, nurses and management

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Jolanda de Bie

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The study presented in this thesis was performed at the Institute for Research in Extramural Medicine (EMGO Institute) at the department of Public and Occupational Health, of the VU University Medical Center (VUMC), Amsterdam, the Netherlands. The EMGO Institute participates in the Netherlands School of Primary Care research (CaRe), which was reacknowledged in 2000 by the Royal Netherlands Academy of Arts and Science (KNAW).

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Cover design by: my father, J.H. de Bie, Alphen aan den Rijn.

The photograph originates from our family's private collection and shows my grandmother Lucy Constance Outshoorn-van der Heijden (*1912-1995*), working as a nurse with a colleague and two patients. She is the second figure from the left (partly standing behind her colleague). The photograph is estimated to have been taken in 1934, when she was 22 years old, in the Bergweg hospital in Rotterdam. She did her nursing exam there in 1933. I chose this photograph for the cover because it illustrates the changes in the nursing profession and on a more personal note because I would have liked to discuss this thesis and many other things with her.

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Introduction

1.1 Background

Traditional roles and domains of professionals in health care are subject to ongoing changes. Central to these changes should be the safety of patients and the quality of the care that is provided. This is especially important when the performance of tasks that are traditionally performed by physicians is shifted to other professionals with different educational backgrounds. These shifts can be attributed to attempts to reduce the physician's workload, medico-technical innovations, economical considerations and capacity problems. When tasks are shifted to nurses, other important factors in this change are the professionalisation of nursing, the job satisfaction and career perspectives of nurses, and the wish for flexibility in the involvement of different professionals in the care for patients.[1-4]

When considering the possibilities and desirability of such shifting of tasks, governments and professional organisations are faced with the question of which health care professionals should be allowed to perform which tasks. This is especially important for tasks or procedures that can be considered potentially risky for patients. Although this can encompass a broad range of medical procedures, some procedures may be so risky that patients are subject to unacceptable health risks when these are performed by professionals with insufficient competence or proficiency.

At the level of the health care system various approaches can be adopted in the regulation of professions and their competencies, and in determining which professional should be allowed to perform which procedures. Internationally, various different choices have been made in this respect, with different degrees of emphasis on legislation versus self-regulation. Various European countries have chosen different systems, for instance Belgium, France, Greece, Italy, Luxembourg and Spain have adopted a monopolistic system, involving a total ban on the unauthorised practice of medicine. The United Kingdom, Ireland and Germany adopted a tolerant system, leaving the practice of medicine open to all, while in the Netherlands, Denmark, Finland, Norway and Sweden the legislators have chosen for a mixed system, based on a tolerant approach with the exception of certain medical acts or procedures.[5-8] Specific exceptions to these system approaches are possible in most systems.

This distinction between approaches to the regulation of medical practice originate mainly from the distinction of professionals in a traditional health care setting versus professionals involved in complementary or alternative medicine. When considering physicians and nurses, the legislative approaches may run parallel to the monopolistic, tolerant and mixed systems described above, be it that in a specific country other choices can be made to regulate these professions within the traditional health care system.

1.2 The IHCP Act and the reserved procedures regulations

In the Netherlands, a new system for the regulation of the professions in individual health care was introduced in 1997, with the Individual Health Care Professions Act (IHCP Act; in Dutch Wet op de beroepen in de individuele gezondheidszorg, Wet BIG).[9] The purpose of this Act is to foster and monitor high standards of professional practice and to protect the patient against professional carelessness and incompetence. The Act aims to provide a balance between the freedom of choice for patients and the protection of patients against incompetent or insufficiently proficient care providers.

In the Act the freedom of choice for patients is assured by lifting the monopoly on the performance of medical procedures that was formerly held by physicians in the Netherlands. According to Dutch legislation patients as consumers should be free to choose who provides their care, both in complementary medicine and in the more traditional health care settings. To guarantee sufficient patient safety at the same time, various provisions were included in the Act, such as title protection for certain professionals linked to educational requirements, the registration of professionals in a public register, and a disciplinary code for all registered professionals. In addition, certain restrictions were imposed on the performance of certain procedures that could result in unacceptable health risks for patients if performed by people with insufficient professional competence. These so-called reserved procedures (in Dutch, voorbehouden handelingen) consist of 11 categories of procedures, including surgical procedures, obstetric procedures, catheterisations and endoscopies, punctures and injections. (see Box 1)

Box 1 *The categories of procedures as listed in the reserved procedures regulations*[*]

- Surgical procedures
- Obstetric procedures
- Catheterisations and endoscopies[**]
- Punctures and injections[**]
- General anaesthetic
- Procedures involved in the use of radio-active substances and ionising radiation
- Cardioversion
- Defibrillation
- Electroconvulsive therapy
- Lithotripsy
- Artificial insemination

[*]*In Dutch: heelkundige handelingen, verloskundige handelingen, catheterisaties en endoscopieën, puncties en injecties, narcose, het gebruik van radioactive stoffen en ioniserende straling, cardioversie, defibrillatie, electroconvulsieve therapie, steenvergruizing en kunstmatige fertilisatie.*
[**]*Nurses have a functional independent status for these categories of procedures (in Dutch, functionele zelfstandigheid)*

Reserved procedures may only be performed by professional practitioners with direct authorisation (e.g. physicians) within their field of expertise and, under certain conditions, by other professionals on the orders of these practitioners (e.g. nurses or practice assistants). There must be reasonable grounds for assuming that the professional receiving the order is proficient enough to perform the procedure properly, as determined by both the physician and the professional receiving the order. If necessary the physician has to give instructions to the nurse, and the nurse must follow the instructions given by the physician. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. In emergency situations the reserved procedures regulations are not applicable. If the reserved procedures regulations are not adhered to, both of the professionals involved are punishable by law.

For certain reserved procedures it is stipulated in the regulations that nurses have a functional independent status, which implies that when nurses receive orders for these procedures arrangements for supervision or the possibility for intervention are not necessary.

1.3 Objective

This thesis describes the practices, policies and perspectives of various professionals and management of institutions with regard to the performance of reserved procedures and other risky procedures. The studies that provided the basic data for this thesis were conducted as part of the evaluation of the Individual Health Care Professions Act. To be able to include a large number of different groups of professionals from diverse health care settings a survey study was conducted. The professional groups that were approached for the study were chosen to include groups of professionals for which a number of different elements of the IHCP Act were of relevance in their practice. Besides the reserved procedures regulations this included registration in the register for Individual Health Care Professionals (IHCP register, in Dutch BIG-register), linked tot title protection and a disciplinary code. Included in the studies used for this thesis were gynaecologists, internists, general practitioners, psychiatrists and nurses (working in general and academic hospitals and for home care organisations). Where relevant, these professionals were also asked questions about professionals that they worked with. General practitioners were also questioned about practice assistants and psychiatrists were also asked questions about health care psychologists, socio-psychiatric nurses and social workers.

The main objective of the research was to provide an empirically based insight into the functioning of the reserved procedures regulations in the Netherlands. In hospital care, primary care and mental health care settings studies

were performed at the level of professionals and institutions. Also addressed in view of the results, was the question of whether or not the reserved procedures regulations provide patients with sufficient protection, but at the same time are flexible enough to take into account shifting of tasks and other ongoing developments in health care.
The following research questions are addressed in the thesis:

1 How have the reserved procedures regulations been converted in practice?
2 Which problems are experienced in daily practice with the reserved procedures regulations?
3 What are the perspectives of different professionals and management with regard to the safety of the performance of reserved and other risky procedures?

1.4 Respondent groups

To include representative groups of professionals, random samples of nurses (n=3200), gynaecologists (n=250), internists (n=350) and psychiatrists (n=300) were drawn from IHCP register. Because this register contains no information about employment, currently employed professionals could only be selected on the basis of their answers to the questionnaires. Subgroups of nurses working in general and academic hospitals (n=687) and home care organisations (n=202) were formed on the basis of their answers concerning their current employment. A random sample of 400 general practitioners was drawn from the NIVEL register of general practitioners. These respondent groups were found to be representative.[10]

Databases provided by the Health Care Inspectorate were used to approach the Board of Directors or management of institutions. In the Netherlands, all 117 general and academic hospitals, 44 general psychiatric hospitals, 61 regional institutions for ambulatory mental health care (in Dutch the RIAGG) and 116 home care organisations were approached.

1.5 Questionnaires

Questionnaires were designed specifically for each of the different respondent groups. Medical, legal and nursing experts from within and outside the research group reviewed all questionnaires in advance. During the preparation of the questionnaires interviews were also held with different experts in the field of nursing, home care, general practice, practice assistance, psychiatry and health law. (see appendix I for an overview of the questions included in the different questionnaires, in Dutch)

1.6 Outline of the thesis

The study was conducted in three different health care settings: hospital care (Chapters 2,3 and 4), primary care (Chapters 5 and 6) and mental health care (Chapter 7). Chapters 2 to 7 are based on articles that have either been published before or have been submitted for publication. Because of this structure of the thesis and in order to enable readers to read each chapter separately some repetition of the same or similar information and explanations was inevitable. This repetition applies in particular to the explanation of the reserved procedures regulations, the same or similar elements of the questionnaires and information about samples.

The knowledge of physicians and nurses concerning the reserved procedures regulations, their performance of such procedures and the manner in which orders are given are described in Chapter 2. Their views concerning the practicability and functioning of these regulations are also presented. Chapter 3 focuses on the policies concerning the reserved procedures regulations that were developed in hospitals, and the views of the management of hospitals with regard to the reserved procedures regulations. Also described is the adherence of nurses to the guidelines that were available to them. Chapter 4 discusses dilemmas' that can possibly occur in daily practice when the reserved and non-reserved procedures are performed by nurses. The occurrence, nature and reasons for problems with and (contemplated) refusals of orders given by physicians to nurses are presented, as well as the views of physicians and nurses concerning the safety of the performance of these procedures by nurses.

Chapter 5 describes the practice and views of nurses in home care concerning the reserved procedures regulations, their adherence to guidelines for these procedures provided by home care organisations, and also dilemmas that occur in the performance of reserved and non-reserved procedures. A description is also given of policies concerning these regulations that have been developed by home care organisations, and their views on the functioning of these regulations within their organisation. Chapter 6 examines practices and experiences with regard to the performance of reserved and non-reserved procedures by practice assistants in general practice. Attention is also paid to the views of general practitioners on the safety of performance of reserved and non-reserved procedures by practice assistants. Dilemmas that they experienced when giving orders for these procedures to practice assistants to perform these procedures and with triage by practice assistants, are also discussed.

Chapter 7 describes the experiences and views of psychiatrists with regard to risky procedures in psychiatry and the safety of the performance of specific procedures by other professionals, the existence of guidelines, and the need to include psychotherapy in the reserved procedures regulations. Also presented

are the views of the management of mental health care institutions with regard to risky procedures within their organisation and the functioning of the reserved procedures regulations.

Chapter 8 is a general discussion of the findings reported in the previous chapters. In order to answer the research questions presented in the introduction to this thesis and to provide a comprehensive review, the data derived from different health care settings is compared and discussed in light of the regulation of the performance of medical procedures, developments in the various health care professions and arising issues concerning patient safety. In appendix I an overview of the questions asked (in Dutch) is given, for the various professional groups and the management of institutions. In appendix II a list is given of the translations used in this thesis for specific Dutch words relating to legislation and health care.

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2

Reserved procedures in Dutch Hospitals

knowledge, experiences and views of physicians and nurses

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Abstract

Introduction
The Individual Health Care Professions Act came into force in the Netherlands in 1997, introducing a mixed system for the regulation of the practice of medicine. One of its components, the reserved procedures regulations, was studied in hospitals to gain insight into the knowledge, experiences and views of physicians and nurses with regard to these regulations.

Method
Questionnaires were sent to representative samples of 250 gynaecologists, 350 internists, and 3,200 nurses, response rates were 65%, 60% and 71% respectively.

Results
Almost all respondents were aware that physicians are authorised to perform reserved procedures on their own initiative (93-99%), and 48-63% knew that nurses are not authorised to do this. A substantial percentage of the nurses performed reserved procedures on their own initiative (17-53%). A majority of gynaecologists and internists presumed that the hospital had ensured the proficiency of the nurses to perform reserved procedures (58% resp. 65%), while 82% of the nurses determined their own proficiency for each procedure. Most respondents felt that the reserved procedures regulations offer adequate protection for patients (58-72%).

Conclusion
Although recommendations are made for improvement, the functioning of the reserved procedures regulations in hospitals is considered to be moderately positive.

2.1 Introduction

Various systems for the regulation of health care professions and their competencies are conceivable, and in various European countries different systems have been chosen. Belgium, France, Greece, Italy, Luxembourg and Spain have adopted a monopolistic system, involving a total ban on the unauthorised practice of medicine. The United Kingdom, Ireland and Germany have a tolerant system, leaving the practice of medicine open to all, while in the Netherlands, Denmark, Finland, Norway and Sweden the legislators have chosen for a mixed system, based on a tolerant approach with the exception of certain medical acts or procedures.[1-4]

This system-based approach to legislation concerning the practice of medicine has been used primarily to differentiate between the legal status of traditional and alternative (or complementary) medicine. When considering physicians and nurses, the legislative approaches may run parallel to the monopolistic, tolerant and mixed systems described above, be it that in a specific country other choices can be made to regulate these professions within the traditional health care system. Although for practical reasons the performance of certain medical procedures by nurses will take place in all systems, its regulation can take place in various ways, depending in different degrees on self regulation, legislation and jurisprudence. In the monopolistic Belgian system, for instance, in spite of the monopoly of physicians, a list of procedures that nurses are allowed to perform on the physician's orders (e.g. intramuscular injections), was determined by Royal Decree.[5] Likewise in the tolerant system in the United Kingdom some diseases (e.g. cancer and diabetes) may only be treated by physicians.[2]

In the Netherlands the mixed system was introduced in 1997, with the Individual Health Care Professions Act (IHCP Act, in Dutch: Wet BIG), replacing a monopolistic system. While adopting a tolerant approach and opening up the practice of medicine, a monopolistic element was maintained by including provisions in the Act restricting the performance of certain procedures that would pose unacceptable health risks to patients when performed by people with insufficient professional competence. These procedures are called *reserved procedures*, because they may only be performed by two groups of professional practitioners: those with direct authorisation (e.g. physicians) and those who may, under certain conditions, perform the procedure on the orders of those with direct authorisation (e.g. nurses). The reserved procedures regulations are explained in more detail in Box 1.

Before the introduction of the IHCP Act, the delegation of procedures by physicians to nurses was informally regulated in the so-called extended arm construction, developed in jurisprudence from 1952 onwards, because of a prac-

tical need for delegation. In this construction nurses who performed the procedures did not have direct authorisation, but were considered to be merely the extended arm of the physicians who held authorisation.[6] A drawback of this informal regulation was that the nurse's own responsibility for the performance of procedures was not acknowledged. The division of accountability of the professionals involved was unclear, and in addition it led to confusion regarding 'who is allowed to do what'.[7,8]

Little empirical evidence can be found about the manner in which potentially risky procedures, such as the reserved procedures in the Netherlands, are being performed by nurses in hospitals, although some descriptive literature and case studies are available. In addition, some studies have reported on the substitution of care, although these focus predominantly on primary care and care provided by nurses with extra training, such as nurse practitioners.[e.g. 9-11]

Box 1 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions: 1. There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2. If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

As was required in the IHCP Act, an evaluation of its functioning was carried out within 5 years after its implementation, at the request of the Dutch Ministry of Health. The current paper reports on the functioning of the reserved procedures regulations in Dutch hospitals, which was studied as part of this evaluation. The research questions were:

1) How much knowledge do physicians and nurses have about the reserved procedures regulations?

2) How often, and in which manner, are reserved procedures performed, and how do physicians and nurses perceive the practicability of the reserved procedures regulations?

3) What are the views of physicians and nurses about the reserved procedures regulations?

2.2 Methods

2.2.1 Study population

As part of the Individual Health Care Professions Act evaluation study a questionnaire was sent to 600 physicians (250 gynaecologists and 350 internists) and 3,200 nurses in the period from July to October 2001. Random samples were drawn from the Register of Individual Health Care Professionals (IHCP register, in Dutch: BIG-Register). Included in the samples were gynaecologists and internists who had been registered before January 2001 and had no restrictions or clauses concerning their registration, were born after 1-1-1937, and were living in the Netherlands. For nurses the same inclusion criteria applied, with the exception of date of birth; only nurses born after 1-1-1942 were included, due to an expected younger retirement age of nurses. No information about current employment status was available prior to drawing the samples. Respondents in the sample who were currently employed in an academic or general hospital were subsequently included for this paper.

2.2.2 Measurement instrument

Anonymous postal questionnaires were sent to the physicians and nurses. For comparability reasons the questionnaires were designed to be as similar as possible. To ensure that all important issues had been included in the questionnaires they were reviewed by medical, nursing, and legal experts. The questionnaires contained questions on knowledge, experiences and views regarding the reserved procedures regulations, and background variables. The knowledge questions concerned the authorisation status of different professionals, and elements of the reserved procedures regulations that were not clear.

Questions about the experiences with reserved procedures included estimates of the monthly performance of injections (intramuscular, intravenous and subcutaneous), catheterisations of the bladder and insertion of peripheral infusions. Questions were also asked about the usual practice concerning giving or receiving orders for injections and catheterisations of the bladder: reasons for giving orders, type of orders that were given, instructions that were given, arrangements for supervision and possibilities for intervention, ways in which proficiency was determined, orders that were passed on from another nurse or via a protocol, and the practicability of the conditions for delegation. Finally, respondents were asked to give their views on the current reserved procedures regulations.

Percentages and simple counts are presented. In addition group differences for gender, age (<30, 30-45, >45) and parttime (<36 hours) or fulltime (≥ 36 hours) employment were analysed with logistic regression analysis.

2.3 Results

2.3.1 Response rates

Of the questionnaires sent to the gynaecologists and internists, nine (3 and 6, respectively) were returned unanswered, due to change of address or retirement. Of the remaining 247 gynaecologists, 160 responded (65%), and after selection on employment status 152 gynaecologists were included. Of the remaining 344 internists, 207 responded (60%), and after selection on employment status 190 internists were included. Of the 3,200 questionnaires sent to nurses, 58 were unanswered due to change of address or retirement. Of the remaining 3,142 nurses, 2,233 responded (71%), and after selection on employment in a general or an academic hospital, 687 nurses working in hospitals were included (assuming response patterns were similar for nurses from different settings, also 71%). When reference is made to nurses in this chapter this refers to the subgroup of nurses working in hospitals.

2.3.2 Knowledge of the reserved procedures regulations

Almost all gynaecologists, internists and nurses were aware of the fact that physicians have direct authorisation for the performance of reserved procedures (95%, 93% and 99%, respectively). However, they were less knowledgeable about the position of nurses; almost half of the gynaecologists and internists (48% resp. 43%) and 63% of the nurses were aware that nurses are not allowed to perform reserved procedures on their own initiative.

Questions were also asked to determine whether or not the different elements of the regulations were clear to the respondents, as shown in Table 1. There was least confusion about which procedures physicians have direct authorisation for (15-30% not clear). Other elements were less clear to the respondents: approximately half of the respondents indicated that it was not clear to them how the instructions should be given or how the responsibility for the performance was divided (44-54% resp. 46-50%). More than two-thirds of the gynaecologists and internists (70% resp. 69%) indicated that it was not clear to them how the proficiency of nurses should be determined. One third of the nurses (33%) indicated that it was not clear to them how they should determine their own proficiency. The majority of the respondents (57-63%) indicated that the manner in which supervision and the possibility of intervention by physicians should be arranged was not clear to them.

Questions were also asked about the various penal provisions made in the

IHCP Act. Approximately 80% of the respondents (gynaecologists 82%, internists 80%, nurses 81%) knew that it was illegal for an unauthorised person to perform a reserved procedure. When asked about the performance of reserved procedures without the required proficiency 65% of the gynaecologists, 76% of the internists and 84% of the nurses correctly indicated that this is illegal.

Table 1 *(Un)clarity of different elements of the reserved procedures regulations: answers 'not clear' from gynaecologists, internists and nurses (percentages)*

	Gynaecologists *n*=145	Internists *n*=189	Nurses *n*=673
Which procedures are reserved to physicians	15	30	15
Which procedures can be performed by nurses without the possibility of supervision or intervention	43	59	31
In which manner orders for reserved procedures should be given	40	32	20
In which manner proficiency should be determined	70	69	33
In which manner instructions should be given	54	44	47
In which manner the possibilities of supervision and intervention should be arranged	63	59	57
The division of responsibility when giving (and accepting)* orders	47	50	46

**The text between brackets was added only for the nurses*

2.3.3 Number of performed reserved procedures

When asked to give an estimate of the number of orders per month that were given for certain reserved procedures, approximately 90% of the gynaecologists indicated that they had given orders to nurses for intramuscular injections a median of 20 times per month, and for catheterisations of the bladder a median of 10 times per month. For the remaining procedures a larger percentage of gynaecologists performed the procedures themselves more often than they gave orders to nurses. Those who gave orders to nurses for inserting a peripheral infusion (44%) did this a median of 10 times per month, and those who gaveorders to nurses for intravenous injections (34%) did this a median of 8 times per month (Table 2).

The percentage of internists who gave intravenous injections and inserted peripheral infusions themselves was almost equal to the percentage of internists who gave nurses orders to perform these procedures (60% resp. 57% and 73% resp. 69%), although, they performed these less frequently themselves than they gave orders to nurses (3-4 times as many orders) (Table 2).

Approximately 80% of the nurses indicated that they received orders to give intramuscular and subcutaneous injections (83% resp. 80%, median 8 resp. 12 times a month). However, there were also nurses who indicated that they performed these procedures on their own initiative (17-53%) (Table 2). Male nurses were more likely to have performed intramuscular and subcutaneous injections on their own initiative (respectively Odds Ratio (OR)=0.507, p=0.016; OR=0.565, p=0.048), as well as having inserted a peripheral infusion on their own initiative (OR=0.452, p=0.003). Full time employed nurses were more likely to have performed intramuscular and intravenous injections on their own initiative (respectively OR=1.941, p=0.007; OR=1.872, p=0.017), as well as having inserted a peripheral infusion both on order and on their own initiative (respectively OR=1.87, p=0.02; OR=1.829, p=0.003). Nurses older than 45 were less likely to have performed intramuscular and subcutaneous injections on order as compared to nurses younger than 30 (OR=4.678, p<0.001; OR=6.103, p<0.001) and between 30 and 45 (respectively OR=2.275, p=0.001; OR=1.957, p=0.004). Nurses older than 45 were more likely to have performed intramuscular injections on their own initiative as compared to nurses younger than 30 (OR=0.412, p=0.011), and nurses between 30 and 45 (OR=0.601, p=0,049).

2.3.4 Reasons for and manner of giving and receiving orders

From Table 3 it can be seen that the reasons most frequently given by gynaecologists and internists for ordering a nurse to give intravenous or intramuscular injections, or for catheterisation of the bladder (female) were that the nurse could do it just as well (83% reason for orders for injections given by both specialists, 86% reason for catheterisation given by gynaecologists) or could even do it better (72% reason for catheterisation of the bladder given by internists). Two thirds of them (63-66%) (also) gave as a reason that they were usually too busy to carry out these procedures.

The answers given by the internists and nurses with regard to the way in which orders for injections or catheterisation of the bladder were given or received were fairly similar. Orders to give injections were always or usually given or received in writing by 70% and 72% respectively. Approximately one third of the internists and nurses (39% resp. 37%) and 62% of the gynaecologists always or usually gave or received verbal orders for catheterisation of the bladder, without written confirmation. When asked about the type of orders, 21-39% of the gynaecologists, internists and nurses stated that they usually gave or received orders only once for multiple performances of injections. Over one third (35%) of the gynaecologists indicated that the orders they usually gave for catheterisation of the bladder were 'when necessary' or 'if .. then'.

Approximately one third of the nurses usually received orders for injections or catheterisation of the bladder via a protocol (36% resp. 34%) (Table 4).

Table 2 *Estimated number of times per month gynaecologists and internists perform reserved procedures themselves and give orders for these to nurses, and number of times per month nurses perform these procedures on the orders of a physician and without orders on their own initiative (percentages)*

	Gynaecologists *n*=147				Internists *n*=190				Nurses *n*=656			
	Self-performance *n*=144-147		Order to nurse *n*=145-147		Self-performance *n*=184-186		Order to nurse *n*=185-190		Order from physician *n*=628-656		Own initiative *n*=558-587	
	%>0	median/ range	%>0	median/ range	%>0	median/ range	%>0	median/ range	%>0	median/ range	%>0	median/ range
▪ Injections intravenous (directly)	65	2/1-25	34	8/1-70	60	5/1-100	57	15/1-800	59	15/1-900	17	5/1-500
▪ Insertion peripheral infusions	79	4/1-30	44	10/1-100	73	5/1-60	69	20/1-200	37	6/1-300	29	5/1-100
▪ Injections intramuscular	31	2/1-25	92	20/1-400					83	8/1-500	22	5/1-300
▪ Injections subcutaneous					11	2/1-20	86	20/1-240	80	12/1-560	22	10/1-200
▪ Catheterisation of the bladder (female)	78	5/1-25	90	10/1-80	13	1/1-3	79	5/1-100	65	3/1-130	53	2/1-70

Table 3 *Orders from gynaecologists and internists to nurses and orders received by nurses for intramuscular injections, intravenous injections and catheterisation of the bladder (female): reason, way and type of orders, instructions, and arrangements of supervision and possibility of intervention (percentages)*

	Gynaecologists		Internists		Nurses	
	i.m. injections *n*=136	Cath. bladder *n*=133	i.v. injections *n*=108	Cath. bladder *n*=145	i.m. injections *n*=551	Cath. bladder *n*=444
Reason why order was given (yes)						
▪ A nurse can do this just as well as I can	83	86	83	57		
▪ A nurse can do this better than I can	33	10	15	72		
▪ I am usually too busy to do this	64	63	65	66		
▪ I do not find it challenging to do this	31	30	32	35		
Way of giving an order (always/usually)						
▪ In writing	27	12	70	37	72	35
▪ Verbally, without written confirmation	38	62	13	39	15	37
▪ Verbally, with written confirmation	40	20	42	34	35	27
Types of orders (usually)						
▪ 'When necessary' or 'if .. then' orders	22	35	9	15	38	25
▪ One order for multiple performances	21	15	30	9	39	12
Instructions about (always/usually)						
▪ The method in general	5	6	11	4	6	5
▪ The method for this patient	9	11	13	6	5	6
▪ The possible complications and side-effects	5	4	28	4	5	5
Arrangements of supervision/ intervention (always/usually)						
▪ Direct supervision in situ	5	6	9	1	8	12
▪ Physicial intervention if something goes wrong	13	15	30	17	20	20
▪ Availability at a distance	80	79	83	77	65	63
▪ Retrospective check	16	19	26	17	12	11

Over half of the nurses indicated that orders to carry out these two procedures were sometimes passed on from other nurses (60% resp. 57%), and three quarters stated that orders for these procedures were seldom or never delegated by a superior (both 75%).Instructions about the way in which these procedures should be carried out or information on possible complications or side-effects were not often given (4-28%). The arrangements made for supervision and intervention mainly consisted of availability at a distance (63-83%) (Table 3).

Table 4 *Types of orders given to nurses for intramuscular injections and catheterisation of the bladder (female) (percentages)*

	Intramuscular injections *n*=549			Catheterisation bladder *n*=444		
	Usually	Some-times	Seldom/ Never	Usually	Some-times	Seldom/ Never
▪ One order for one specific performance	24	53	23	43	40	17
▪ One order for multiple performances	39	35	26	12	31	57
▪ Orders via protocol	36	32	32	34	32	35
▪ 'When necessary'or 'if .. then' orders	38	39	23	25	38	38
▪ Orders passed on from another nurse	7	60	33	7	57	36
▪ Orders delegated by a superior	6	20	75	5	20	75

2.3.5 Determining proficiency

The gynaecologists and internists were also asked about the way in which they determined the proficiency of a nurse to perform a reserved procedure. Of the gynaecologists and internists, 9% and 3%, respectively, stated that they never gave orders to nurses to perform reserved procedures. The way that was most frequently mentioned by the gynaecologists and internists who did give orders to nurses to perform reserved procedures was that they assumed that the institution had ensured the proficiency of the nurses (58% resp. 65%). Moreover, they assumed proficiency based on the training of the nurses or they determined their proficiency per procedure (55% resp. 54%, 53% resp. 41%) (Table 5).

The nurses were asked how they determined their own proficiency when they received orders from a physician to perform a reserved procedure. Reserved procedures were not performed at all by 2% of the nurses. The great majority (82%) of those who did perform reserved procedures said that they determined their own proficiency per procedure. Approximately half of the nurses assumed that they were proficient on the basis of their training (52%) and/or had a certificate of proficiency from the hospital (50%) for one or more

reserved procedures (i.e. a certificate listing the procedures for which a professional is proficient) (Table 5).

Table 5 *Ways in which gynaecologists and internists determine the proficiency of nurses and ways in which nurses determine their own proficiency when giving and receiving orders for reserved procedures (percentages)*

	Gynaecologists *n*=135	Internists *n*=180	Nurses *n*=670
▪ I assume that the institution where I work has ensured the proficiency of the nurses	58	65	
▪ I assume the proficiency of the professional on the basis of the training completed*	55	54	52
▪ I determine per procedure the proficiency of the professional to perform the procedure*	53	41	82
▪ I determine per patient the proficiency of the professional to perform the procedure*	22	12	28
▪ I consider this to be the responsibility of the professional**	24	21	4
▪ I have a certificate of proficiency for one or more reserved procedures			50
▪ I determine my proficiency on the basis of a protocol			37

**For nurses: my own proficiency, or whether or not I am proficient*
***For nurses: I consider this to be the responsibility of the physician*

2.3.6 Practicability of the conditions

Of the gynaecologists, internists and nurses 61%, 69% and 71% respectively stated that the reserved procedures regulations with regard to giving and receiving orders were partially or totally practical. Approximately 10% considered the regulations to be unpractical (6-14%) and the rest were 'unsure' (22-25%).

The gynaecologists and internists who were of the opinion that the requirements were impractical mentioned, among other things, problems with regard to the written confirmation of verbal orders, the administrative 'red tape', determining the proficiency of nurses, and the physical problems involved in providing supervision and intervention. They also indicated that strict adherence to the regulations was not always possible, due to lack of time, and that the IHCP Act was far removed from the reality of daily practice. The nurses who thought that the regulations were partially or totally unpractical mentioned, in particular, that they had problems with regard to orders that were given by telephone or verbally (mostly obtaining written confirmation). They also indicated that it was not always possible to adhere to the regulations because of the pressure of work or a shortage of personnel, that the regulations are not (totally) clear, and that they also experienced problems with regard to the determination of proficiency and the possibility of supervision and intervention. In particular, those respondents who were not certain whether the

requirements were practical, said that they did not know enough about the reserved procedures regulations and the requirements for giving and receiving orders.

2.3.7 Views regarding the current reserved procedures regulations

Of the gynaecologists, internists and nurses 72%, 69% and 58% respectively were of the opinion that the reserved procedures regulations provide adequate protection for the patient. More than three quarters of the nurses (78%) and approximately half of the gynaecologists and internists (50% resp. 55%) considered the reserved procedures regulations to be an improvement on the previously applicable legislation. Approximately half of the nurses (49%) and over 40% of the gynaecologists and internists (41% resp. 42%) were of the opinion that the reserved procedures regulations are closely linked to daily practice. The opinion of approximately one third of the gynaecologists, internists and nurses (31-37%) was neutral in this respect. (Table 6)

Table 6 *Views on the reserved procedures regulations: gynaecologists, internists and nurses who agree (totally or somewhat) with the statements (percentages)*

	Gynaecologists *n*=148	Internists *n*=187	Nurses *n*=681
▪ Patients are adequately protected by the reserved procedures regulations	72	69	58
▪ The reserved procedures regulations are an improvement on the previously applicable legislation	50	55	78
▪ The reserved procedures regulations are closely linked to daily practice	41	42	49
▪ In my work I have experienced no changes due to the reserved procedures regulations	47	53	42
▪ The list of reserved procedures is adequate for my work situation	47	55	67
▪ The reserved procedures regulations imply too many restrictions for me	23	26	11

Around half of the gynaecologists and internists (47% resp. 53%) and 42% of the nurses stated that the reserved procedures regulations had made no difference with regard to their work. Nurses older than 45 were more likely to agree with this statement as compared to nurses younger than 30 (OR=2.035, p=0.012). The majority of the internists and nurses (55% resp. 67%) and 47% of the gynaecologists considered the list of reserved procedures adequate for their work situation. A minority of the respondents (11-26%) was of the opinion that, for them, the reserved procedures regulations imply too many restrictions (Table 6).

2.4 Discussion

The aim of the current study was to evaluate the functioning of the reserved procedures regulations in Dutch hospitals. Unfortunately, it was not possible to perform an effect analysis with either a before-after or a control group design after the implementation of the IHCP Act in the Netherlands. The data, nevertheless, provide a valuable and extensive description of the functioning and practice with regard to the reserved procedures regulations in Dutch hospitals. The response rates were high, and because anonymity was guaranteed it is thought that the physicians and nurses responded honestly.
Our results show that gynaecologists, internists and nurses have some knowledge of the reserved procedures regulations, although there are some important limitations. This concerns not only limitations in the knowledge of 'who is allowed to do what', but also a lack of clarity concerning the regulations with regard to giving orders, especially the determination of proficiency, the way in which instructions should be given, and the arrangements for possible supervision and intervention.

Furthermore, our data show that the majority of nurses performs reserved procedures on the orders of a physician on a regular basis. Strikingly, a substantial number of nurses indicated that they also perform reserved procedures on their own initiative, without the required orders from a physician, although this is illegal and punishable by law. Subgroup analysis showed that male nurses were more likely to perform some of these procedures on their own initiative, the same was true for full time employed nurses, and for intramuscular injections, also for nurses older than 45. The fact that nurses perform these procedures on their own initiative also suggests a shift from physicians to nurses in deciding when a procedure is indicated. However, deciding when a procedure is indicated is not included in the field of expertise for nurses in the IHCP Act, and is currently not part of their formal education. It is not ruled out, however, that a number of nurses interpreted acting on orders via a protocol, as acting on their own initiative.

Even though in most cases the legally required orders were given, the way in which they were given appears to vary considerably. The legally assumed one-to-one relationship between physician and nurse, which implies one single specific order, is often not the case in practice. Orders are given in more general terms ('if .. then' orders) or are passed on from another nurse or via a protocol, which, to a certain extent, again implies shifting the decision making about indication to nurses.

Most of the respondents considered the requirements for giving and receiving orders to be reasonably feasible in practice. They have experienced little change since the introduction of the IHCP Act, and are mainly of the opin-

ion that the Act is practical, albeit that a small minority thinks that it contains too many restrictions. One of the problems that is frequently mentioned is that, in practice, too much administrative 'red tape' is involved. However, this can not always be attributed directly to the IHCP Act.

At the same time, it appears that the legal requirements are not very strictly met in practice. For instance, instructions concerning injections and catheterisation of the bladder are seldom given (although this will often be unnecessary if these procedures are routinely performed) and supervision and intervention often consist of availability at a distance (which is sufficient because nurses have functional independence in these procedures, see Box 1). The common lack of the ideal one-to-one relationship between physician and nurse obviously makes it more difficult to meet the legal requirements for the performance of reserved procedures by order.

Most gynaecologists and internists assumed that proficiency was ensured by the hospital, and did not determine this proficiency for each individual order. Although half of the nurses indicated that they had statements (certificates) of proficiency from the institutions they worked for, it is not clear how this proficiency is tested or whether it is regularly re-tested. It should be noted that the assurance of competence of nurses has more levels in the Dutch health care system than this one-to-one determination of proficiency. Starting with the educational requirements for registration of nurses (linked to title protection, a disciplinary code and a description in the IHCP Act of the field of expertise of nurses), as well as quality assurance and training policies in hospitals. However, proficiency, as described in the reserved procedures regulations, is seen as the current status of the proficiency of an individual nurse, which can vary over different cases, methods and over time due to (recent) work experience.

From the findings it is also clear that the majority of the respondents were of the opinion that the reserved procedures regulations are a provision that provides adequate protection for patients. They also considered that the regulations contained in the IHCP Act (especially for the nurses) were an improvement on the situation in the past.

Obviously, order situations and the performance of procedures by nurses are more complex issues than assumed by the legislator, this is partly due to changes that are taking place in the field of health care, both in the Netherlands and internationally. There is an increase in the delegation of tasks by physicians to nurses, fuelled by shortages of physicians and nurses, budgetary cutbacks, medical technical developments and an increasing demand for more cost effective health care provision.[9-12] It is to be expected that this trend will only increase in the future, involving a further increase in delegation, not only by physicians to nurses, but also by nurses to other health care providers. A

concern with this increase in delegation, however, is that policy decisions with regard to the (legal) framework for these changes will be driven by practical and economical considerations rather than by quality of care considerations.[13,14] If such changes are beneficial and justified, flexible regulation that imposes no restrictions is required. Vigilance is, however, also required to prevent excessive delegation and to guarantee the quality of the care and the protection of patients.

When considering the legislation that applies to physicians and nurses, a monopolistic system may offer patients the most protection, but it may not be flexible enough to adequately respond to these developments in health care. A tolerant system, while offering the most flexibility by giving nurses authorisation to perform certain medical procedures, and also representing a less traditional and hierarchical division of responsibility, may, in its turn, not offer sufficient protection for patients or (legal) safeguards for the quality of the care provided. It is the mixed system, that should, in theory, provide a balance between this flexibility and the protection of patients.

In the Netherlands, the functioning of the mixed system, which includes the reserved procedures regulations in hospitals, can be considered to be moderately positive. To improve the link between legislation and practice, however, some changes are recommended, such as the acceptance of more generic orders where this does not compromise the safety of patients and where this does not imply shifting the entire process of deciding when a procedure is indicated to the domain of nurses. Suggestions have also been made in the Netherlands to expand the authorisation of certain groups of specialised nurses or nurse practitioners.[12,14] Further, confusion with regard to the determination of proficiency may be cleared up when the hospital management plays a greater role in this process. Finally, since knowledge can be seen as a prerequisite for compliance with regulations, more education during training and further dissemination of information to qualified nurses and physicians is necessary to make them aware of the current regulations governing the performance of certain procedures in daily practice.

In the Netherlands discussions are still ongoing in the political and health care professionals arena on the choices that were made in the Dutch system and the role of nurses in the future Dutch Health Care.

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3

Regulations for risky procedures

policies, guidelines, and nurses' adherence in hospitals

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Abstract

Introduction
The aim of this study was to provide an insight in the functioning of the *reserved procedures regulations* in Dutch hospitals. These regulations are part of the Individual Health Care Professions Act (IHCP Act), which came into force in the Netherlands in 1997.

Method
Postal questionnaires were sent to the Board of Directors of all 117 hospitals in the Netherlands and a representative sample of 3200 nurses (response 75% and 71%). Of the nurses 687 currently working in a hospital were included. Main outcome measures were: elements of policy developed in hospitals, presence of guidelines for reserved procedures and adherence of nurses, and views of hospital management on the functioning of the reserved procedures regulations.

Results
All hospitals had some form of policy on the reserved procedures regulations; a minority (41%) had a review and adjustment policy regarding the handling of reserved procedures. Of the nurses 61% fully adhered to institutional guidelines when performing reserved procedures, 39% adhered partially. The reason most frequently mentioned was the situation of the patient (75%). Of the hospitals 71% considered the reserved procedures regulations to provide patients with adequate protection.

Conclusion
It appears that the reserved procedures regulations have resulted in hospital policies and guidelines on these procedures and contribute to the quality of care and the protection of patients. Nevertheless recommendations for improvement are made.

3.1 Introduction

There is an ongoing debate on task shifts from physicians to nurses and other health care professionals and its consequences for the quality and safety of care.[1-5] In hospitals many actors play a role in the assurance of high quality care and the safety of patients, such as the government, the hospitals' management, the individual health care professionals and their professional bodies. The role of the government in this assurance stems from the basic right of patients to receive care for their health, including the right to sufficient quality of care. This right is laid down in national laws as well as in international treaties.[6]

Box 1 *Dutch health care quality legislation: The Care Institutions Quality Act (1996) and the Individual Health Care Professions Act (1997)*

	Care Institutions Quality Act (CIQ Act)	*Individual Health Care Professions Act (IHCP Act)*
Aimed at	management of care institutions (hospitals, nursing homes, psychiatric hospitals etc.)	individual health care professionals (physicians, nurses, dentists, midwives etc.)
replaced regulation	detailed demands on the facilities procedures and care provided that had to be met before being recognised as a care institution	monopoly of physicians on the practice of medicine
basic goal	to make the care institutions primary responsible for the assurance of quality of care in their institutions	to provide a balance between the freedom of choice for patients and their protection in individual health care. The practice of medicine is open to all (reserved procedures excepted)
relevant components	▪ management of care institutions is responsible for the assurance of appropriate care in their institution ▪ systematic attention should be paid to quality of care within the institution ▪ a yearly report on the efforts in quality of care assurance is to be published by the care institutions	▪ registration in IHCP Register for physicians, nurses, dentists, midwives, pharmacists, psychotherapists, health care psychologists, physiotherapists (linked to title protection, a description of nurses' field of expertise and subject to a disciplinary code) ▪ reserved procedures regulations (Box 2) ▪ penal provisions

In the Netherlands, a change in the legislative approach was introduced in the latter part of the 1990s, when several new acts in the field of health care came into force, that put more emphasis on the self regulatory processes within care institutions and among individual health care professionals. These framework laws included the Health Care Institutions Quality Act (CIQ Act 1996; in

Dutch KZI) and the Individual Health Care Professions Act (IHCP Act 1997; in Dutch Wet BIG). (Box 1)

The CIQ Act puts demands on the hospital management in broad terms only, stating that they have to ensure that *appropriate care* (defined as efficient, effective and patient-orientated care) is delivered in their hospital. In addition, they are obliged to implement a cyclic quality assurance system and to publish an annual quality report.[7,8] The IHCP Act applies to individual health care providers, and opens up the practice of medicine to all professionals, replacing the former monopoly of physicians in this field. To ensure adequate protection of patients at the same time, provisions are included to restrict the performance of procedures or medical acts that will pose unacceptable health risks to patients if performed by individuals who do not have the necessary professional competence. These so-called *reserved procedures* are reserved to be performed by two groups of professionals: those with direct authorisation (e.g. physicians) and those who may, under certain conditions, perform the procedures on the orders of those with direct authorisation (e.g. nurses). A list of general categories of reserved procedures as listed in the IHCP Act, is displayed in Box 2, as well as the conditions necessary for the authorised performance of reserved procedures on the orders of a physician.

Box 2 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions: 1. There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2. If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

One of these conditions is the determination of the nurse's proficiency by both professionals, seen as the current status of proficiency to perform the reserved procedure, which can vary over time due to (recent) work experience. In addi-

tion to this assessment of proficiency, nurses' competence is assured by educational requirements for registration as a nurse in the IHCP register, as explained in Box 3.

Box 3 *Registration and education of nurses in the Netherlands*

Registration
The title of nurse can be used only after registration in the IHCP register, the register of health care professionals. Registration in the IHCP register is linked to a disciplinary code as well as a description of nurses' field of expertise. Further qualifications after initial formal education (e.g. a specialisation or nurse practitioners masters degree) are not (yet) registered.

Field of expertise (IHCP Act)
- The performance of procedures in the field of observation, monitoring, nursing and care.
- The performance of procedures in individual health care on the orders of a physician, following the physicians diagnostic and therapeutic work.

Training
A 4 years formal education at a school of Higher Nursing education or an equivalent in-service training is required. In addition to educational requirements for nurses in EU guidelines (77/453, 1977), these include training on quality assurance and health law.

Nursing and midwifery
Nursing and midwifery in the Netherlands are distinct and separate professions, with different educational requirements and authorisations. When referring to nurses in the Dutch context midwives are not included.

It can be expected that Dutch hospitals will have developed policies concerning the reserved procedures regulations, like written guidelines, as a result of the demand for appropriate care stipulated in the CIQ Act. However, the protection that these can offer patients is not only dependent on their presence or content, but also on actual application in practice. Attention should therefore also be paid to the adherence to them. In this respect nurses are of special importance, as most guidelines are intended to be used by them.

The way in which national laws on quality of care are converted in daily practice in health care is an essential aspect when considering the functioning of these specific regulations. In addition the evaluation of this conversion can provide relevant information internationally about the effect of different approaches to the regulation of quality of care. As was required in the IHCP Act, an evaluation of its functioning was carried out within 5 years after it came into force. In the current paper the functioning of the reserved procedures regulations in Dutch hospitals was studied. Specifically the development of policies in hospitals was studied, as well as the adherence of nurses to available guidelines and the views of management of hospitals with regard to the reserved procedures regulations.

3.2 Methods

3.2.1 Setting and study population

Postal questionnaires were sent to the (Boards of) Directors of all 117 hospitals in the Netherlands and a random sample of 3,200 nurses drawn from the Register of Individual Health Care Professionals (IHCP register, in Dutch BIG register), in the period from June to September 2001. Included in the sample were nurses who were born after 1-1-1942, were registered before January 2001 with no restrictions or clauses concerning their registration, and were living in the Netherlands. Information on current employment of professionals is not available in the IHCP register and could therefore not be used as a selection criteria beforehand. For the purpose of this paper, only nurses that reported working in a hospital in the questionnaire, were included.

3.2.2 Questionnaires

Medical, nursing and legal experts reviewed the questionnaires in advance. The hospital questionnaire contained questions on written policies concerning the reserved procedures regulations, and views on the protection of patients, and the need for reduction in the number of reserved procedures or expansion of the functional independence of nurses. When reference is made to the answers given by hospitals, these are the answers supplied by or via the (Boards of) Directors or management.

The questionnaire for nurses contained questions on the availability in the hospital or on the wards of written guidelines or protocols regarding reserved procedures. Although there is a difference between guidelines and protocols these terms are frequently mistakenly used interchangeable in practice. Therefore, both were combined in the phrasing of the questions, to prevent missing data due to nurse's misunderstanding of the question. When reference is made in this paper to guidelines, this refers to guidelines and/or protocols.

3.2.3 Analysis

The study is descriptive, percentages and simple counts are presented. In addition, chisquare tests were performed to determine group differences between small (<400 beds), medium-sized (400-700 beds) and large (>700 beds) hospitals.

3.3 Results

3.3.1 Response rates

Five questionnaires sent to the hospitals were undeliverable, due to organisational changes or merges. Of the remaining 112 hospitals, 84 responded (75%).

Of all the questionnaires sent to the nurses, 58 were returned empty, due to change of address or retirement. Of the remaining 3,142 nurses, 2,233 responded (71%). After selection on employment in a hospital, 687 hospital nurses were included (under the assumption response patterns for nurses in different sectors is equal, 71%)

3.3.2 Developed policies on reserved procedures

All hospitals indicated that policies had been developed with regard to the reserved procedures regulations. From table 1 it can be seen that 71% had a policy document and 68% a functionary or committee specialised in the (development of) policies on the reserved procedures regulations.

Table 1 *Elements of policy on the reserved procedures regulations in all hospitals together, and in small, medium-sized and large hospitals (percentages)*

	All	Small	Medium	Large
	n=84	*n*=38	*n*=26	*n*=19
Policy statement on reserved procedures	71	74	73	68
Description of the reserved procedures that are performed in the hospital	82	79	77	95
Functionary or committee responsible for the policy concerning reserved procedures	68	63	73	74
Training and education policy for the performance of reserved procedures by professionals	87	84	85	95
Protocols/guidelines				
▪ for certain reserved procedures	39	42	54	16*
▪ for all reserved procedures	56	53	39	84*
▪ not present	5	5	8	-
Proficiency declarations for the performance of reserved procedures				
▪ for individual professionals	69	68	69	68
▪ for professional groups	23	13	31	32
▪ not present	26	26	27	26
Written review and adjustment policy with regard to dealing with reserved procedures	41	45	35	42

**significant difference compared to other hospitals (small and medium-sized combined)*

A description of the reserved procedures that were being performed in the hospital was present in 82% of the hospitals. Just over half of the hospitals had developed guidelines for the performance of all reserved procedures (56%), while 39% had developed these for specific reserved procedures; 5% had not developed any guidelines. Proficiency declarations for the performance of reserved procedures (i.e. a certificate listing the procedures for which a profes-

sional is proficient) for individual professionals were used in 69% of the hospitals, while 23% (also) used proficiency declarations for groups of professionals. In 26% of the hospitals proficiency declarations were not used.

Most hospitals (87%) indicated that they had developed an educational and training policy for professionals regarding the performance of reserved procedures. A written review and adjustment policy regarding the handling of reserved procedures had been developed in 41% of the hospitals. (Table 1) Large hospitals more often had developed guidelines for all reserved procedures that were being performed in their hospital, compared to the rest of the hospitals (p=0,004).

3.3.3 Nurses' practice concerning guidelines

Of the nurses, 87% indicated that guidelines on reserved procedures were present in the hospital or on the wards. When describing the content of the guidelines, the procedures for which the arrangement of possible intervention or supervision is not obligatory were mentioned most frequently (82%). Approximately 40-50% of the nurses (also) mentioned the following elements of the regulations: 'the manner in which an order should be given' (53%), 'the way in which proficiency should be determined' (43%), 'the procedures that are reserved to be performed by physicians (42%) and 'the conditions for accepting an order' (38%) (Table 2).

Table 2 *Content of guidelines on reserved procedures provided in the hospital or on the ward according to responding nurses (percentages, more than one answer could be given)*

	n=576
▪ Description of the procedures for which the possibility of intervention or supervision is not obligatory (*functional independence*)	82
▪ The manner in which an order for a reserved procedure should be given	53
▪ The way in which proficiency should be determined	43
▪ The procedures that are reserved to be performed by physicians	42
▪ The conditions for accepting an order for a reserved procedure	38
▪ Description of manner in which possibility of supervision and intervention should be determined	24
▪ The division of responsibility in giving and accepting orders	23
▪ The manner in which instructions should be given	20

Of the nurses, 61% indicated they fully adhered to the guidelines when performing reserved procedures, while 39% adhered partially (two did not adhere to these guidelines at all). The reason mentioned most frequently for not fully

adhering was 'the situation of the patient' (75%). Other reasons included: 'the guidelines are not practical enough' (38%), 'not (fully) informed of the content of the guidelines' (27%), 'lack of time' (24%) and 'the guidelines are not formulated/written clearly (10%).

3.3.4 Perceived protection of patients

Of the hospitals 71% experienced the reserved procedures regulations as an instrument that provides patients with adequate protection; 31 hospitals also gave an explanation (Table 3). Most frequently mentioned (25 x) was that the regulations promoted the quality of care, (e.g by education and review (expertise and skills promotion), protocolisation and awareness among professionals about their individual responsibilities). It was also mentioned (7x) that the regulations are only one of the many instruments for the protection of patients, together with the policy of the organisation, education and guidelines.

Table 3 *Views of (Boards of) Directors of hospitals concerning the reserved procedures regulations in hospitals, perceived protection of patients and need for changes in the reserved procedures regulations (percentages)*

	n=84		
	Yes	No	Don't Know
Protection			
▪ The reserved procedures regulations provides adequate protection of patients	71	7	21
Need for changes			
▪ Need for a reduction in the number of procedures that are reserved	4	96	-
▪ Need for an increase in the reserved procedures for which nurses have functional independence*	25	75	-

**Arrangements for supervision or interventions are not obligatory, see Box 2*

3.3.5 Need for changes

Only 3 hospitals (3%) stated that within the organisation there was a need to decrease the number of procedures that fell under the reserved procedures regulations, namely giving injections and the insertion of a peripheral infusion by a nurse.

Of the hospitals 25% indicated that within the organisation there was a need to increase the number of reserved procedures for which no supervision or intervention is obligatory for nurses when performing this procedure on the order of a physician (functional independence, see also Box 2). In this respect, 13 of the 20 hospitals mentioned a total of 10 different procedures (6 procedures were erroneously mentioned for which nurses already have functional independence (e.g. injections and bladder catheterisations)). of the remaining 4

procedures, 3 reserved procedures were mentioned: gynaecological procedures, repositioning a jugular catheter and the removal of certain catheters (including epidural catheters). Furthermore, the tasks of nurse practitioners and specialised nurses were mentioned.

3.4 Discussion

We feel this study gives a reliable overview of the way in which hospitals have converted recent changes in legislation in policies and guidelines, and in which manner this is adhered to in daily practice by nurses. The response rates were high, and because anonymity was guaranteed we believe the hospitals and nurses responded honestly. However, limitations of the study remain that the results are based on self-report and that the study is mainly limited to process-factors.

The results show that all hospitals had developed some form of policy on the reserved procedures regulations. This is in line with our expectations, as hospitals have a responsibility in providing appropriate care, as formulated in the CIQ Act. When considering the actual policies and guidelines that have been developed, it becomes apparent that most hospitals have developed structural components of policy related to the reserved procedures regulations, such as a policy statement, a description of the present reserved procedures and a functionary or committee specialised in the (development of) policies on the reserved procedures regulations in the hospital.

With regard to the developed procedural components, almost all hospitals had developed guidelines on some or all reserved procedures that were performed within the organisation. Large hospitals more often had guidelines for all reserved procedures compared to the other hospitals. This difference might be due to the fact that reserved procedures are performed less frequently in smaller hospitals. Furthermore most of the hospitals had developed training and education policy for professionals, and the majority of them worked with proficiency declarations for individuals and, to a lesser extent, for groups of professionals.

Other research has shown that the majority of physicians (i.e. gynaecologists and internists) assume that hospitals guarantee the proficiency of nurses in the performance of reserved procedures.[9] This study shows that assumption is not justified however, since one quarter of the hospitals did not have proficiency declarations. It is also unclear in which way the proficiency is determined by those hospitals that do use these declarations and whether or not these are periodically assessed. In this respect, it should be noted that declarations of proficiency serve as an aid to determine proficiency, but the responsibility for the assessment of current proficiency remains with the individual

professionals involved in giving and receiving orders for reserved procedures. In addition to the hospital's policies and the individual assessment of proficiency by professionals, nurses' competence is also assured by educational requirements for registration of nurses in the Dutch health care system (linked to title protection, a disciplinary code and a description in the IHCP Act of the field of expertise of nurses).

It is notable that despite the demands of the CIQ Act for a quality assurance system only a minority of the hospitals had developed a review and adjustment policy for dealing with reserved procedures. Therefore (further) promotion of review and adjustment is essential to keep policies and guidelines up-to-date.

Furthermore the results show that a substantial minority of nurses do not (fully) adhere to available guidelines on reserved procedures. Main reason for not doing so was the situation of the patient, although in emergency situations the requirements in the reserved procedures regulations may not apply. In addition, according to the nurses, some of these guidelines were not feasible in daily practice or not formulated clearly. Lack of time and insufficient knowledge of the content of the guidelines (also) seemed to play a role. These nurses should receive more information about the (legal) regulations that influence their daily practice, either by the hospitals, professional associations of nurses or through governmental informational campaigns.

The majority of hospitals felt that the reserved procedures regulations provided patients with adequate protection, in particular through quality promotion. Markedly there was a certain lack of knowledge among the management of the hospitals, not only with regard to the procedures that fall under the reserved procedures regulations, but also the reserved procedures for which nurses have a functional independence. As knowledge about the legal regulations governing daily practice at management level is an initial prerequisite for adherence to these regulations in hospitals, more information is needed in the hospitals. Also notable was the fact that various hospitals felt the need to increase the functional independence of nurses with regard to tasks carried out by nurse practitioners and specialised nurses. This reflects the current developments in which new jobs are created and task shifts take place.

Although for practical reasons shifting of tasks traditionally done by physicians to nurses will take place in all health care systems, its regulation can take place in various ways, with different degrees of emphasis on self regulation versus legislation. Approaches in legislation range from a monopolistic approach, in which the performance of medical procedures is restricted to physicians (e.g. Belgium), to a tolerant approach allowing all professionals in health care to perform medical procedures (United Kingdom).[9] Legally regulated exceptions to these rules in either system can occur. In the Netherlands a

mixed system, containing both monopolistic as well as tolerant elements was adopted with the introduction of the IHCP Act and the reserved procedures regulations.

In conclusion, it appears that this approach, and specifically the reserved procedures regulations, have resulted in hospital policies and guidelines on the reserved procedures regulations and contribute to quality of care and the protection of patients in hospitals. Nevertheless there is certainly room for improvement, which is reflected in the above-mentioned recommendations.

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4

Reserved and other risky procedures by nurses in hospitals

problems, (contemplated) refusals and perspectives of physicians and nurses

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Abstract

Introduction
New Dutch legislation on the professions in individual health care came to force in 1997 with the introduction of the Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG). One element of this Act is the reserved procedures regulations. This study is aimed at possible dilemma's that occur in Dutch hospitals when nurses receive orders for reserved and other risky procedures by physicians.

Method
Occurrence of problems with, refusals of orders and contemplated refusals of orders for risky procedures by nurses in Dutch hospitals and views on the safety of performance was studied using postal questionnaires (600 physicians and 3,200 nurses, response 60-71%).

Results
Of the respondents 11-30% experienced problems with and (contemplated) refusals of orders for risky procedures in the previous 12 months. Gynaecologists and internists most frequently mentioned problems concerning the practical performance of the procedure (44% and 30% respectively). The reason for a problem or a contemplated refusal most frequently given by nurses was that they disagreed with the medication policy (34% and 35% respectively). The reason for a refusal most frequently given by the gynaecologists, internists and nurses was that the nurses themselves were of the opinion that they did not have the necessary authorisation (95%, 67%, and 62% respectively). With regard to certain procedures, the views of professionals are more strict than the current legal regulations.

Conclusion
The nature and incidence of problems and (contemplated) refusals of orders, do not indicate serious dilemma's on a large scale in daily practice in Dutch hospitals with regard to the reserved procedures regulations.

4.1 Introduction

In recent years there has been a change in the traditional roles of physicians and nurses, motivated by medical-technical developments, capacity problems, and economical considerations. Other important factors in this change are the professionalisation of the nursing profession, the job satisfaction of nurses, their career perspectives, and the lack of flexibility that is experienced in the involvement of different health care professionals. It has for instance been hypothesized that task shifts or changes in skill-mix in health care can improve the continuity of care and the communication with patients. These task shifts can take different forms. Tasks can be delegated 'horizontally' to professionals with an equal level of expertise (e.g by hospital specialists to general practitioners) or 'vertically' to professionals with a lower level of expertise (e.g. by physicians to nurses). Another development is the creation of new functions, such as the nurse practitioner and the physician assistant, that already exist in the USA and the UK.[1-5]

In deciding which elements of care, or which procedures are appropriate for task shifts from physicians to nurses, key considerations are the quality of the care provided to patients and the extent to which these procedures pose a risk to patients when performed by professionals who are not trained as physicians. However, there seems to be no clear consensus on the safety of shifting tasks from physicians to nurses and other professionals. Although some studies have been done on possibilities for task shifts and skill mix changes most of these focussed on local experiments and primarily used patient satisfaction and satisfaction of the involved professionals as outcome measures. One meta-analysis that was done in this respect found large differences for the percentage of possible tasks that could be shifted from physicians to other professionals, ranging from 4 - 90%, although most studies ranged from 25 - 70%.[6] Most of the studies that were analysed focused on task shift and task substitution from physicians to specialised nurses and nurse practitioners in primary care.

When considering the possibilities and desirability of shifting tasks from physicians to nurses, governments and professional organisations are faced with the question of what professionals in health care should be allowed to perform which tasks without compromising patient safety. Various approaches can be chosen with regard to the regulation of performance of medical procedures and internationally different choices are made, with different degrees of emphasis on legislation versus self-regulation.

In the Netherlands, the Individual Health Care Professions Act (IHCP Act, in Dutch: Wet BIG), which came into force in 1997, enables task shifts to take place. The basic principle underlying this Act is that the practice of medicine is open to all, replacing the former monopoly of physicians. Only certain

procedures that would cause unacceptable health risks to patients when performed by professionals with insufficient professional competence, are specifically excluded to ensure adequate protection of patients. These so-called reserved procedures (e.g. injections) may only be performed by two groups of health care professionals: those with direct authorisation (e.g. physicians) and those who may, under certain conditions, perform the procedure on the orders of those with direct authorisation (e.g. nurses). One of these conditions is the determination of the nurse's proficiency by both professionals, seen as an assessment of the current status of proficiency to perform the reserved procedure, which can vary over time due to (recent) work experience. The reserved procedures regulations are explained in more detail in Box 1.

Box 1 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions: 1. There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2. If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

The list of categories of reserved procedures mainly consists of medical-technical procedures that can be clearly defined and demarcated. More medical procedures or actions may also be considered as risky procedures, but these are not reserved, however, because it is more difficult to clearly define and demarcate them (e.g. assessment of the need for sedatives).

As required by the IHCP Act, an evaluation of its functioning had to be carried out within 5 years after its implementation. This study aims to evaluate the functioning of the reserved procedures regulations in hospitals by examining possible dilemma's that occur in daily practice with the performance of

reserved and non-reserved risky procedures by nurses. For this purpose the occurrence, nature and reason for problems with and (contemplated) refusals of orders from physicians to nurses for reserved and non-reserved risky procedures were studied. In addition the views of physicians and nurses on the safety of the performance of these procedures by nurses were obtained.

4.2 Method

4.2.1 Samples

Postal questionnaires were sent to random samples of 600 physicians (250 gynaecologists and 350 internists) and 3,200 nurses (drawn from the register of Individual Health Care Professionals) in the period from July to October 2001. Included in the samples were gynaecologists and internists who were born after 1-1-1937, were registered before January 2001 with no restrictions or clauses concerning their registration, and were living in the Netherlands.

The same inclusion criteria were applied for nurses, with the exception of date of birth; only nurses born after 1-1-1942 were included, due to the expected younger retirement age of nurses. Educational requirements for registration as a nurse in the public IHCP register are described in the IHCP Act (4 years formal education or in-service training). Registration in this register entitles the professional to use the title of nurse and is linked to a disciplinary code as well as a description of the field of expertise of nurses. Further qualifications after initial formal education, such as a nurse practitioner masters degree or a specialisation, are currently not registered. In the Netherlands nursing and midwifery are distinct and separate professions with different authorisations; when referring to nurses midwives are not included. Information on current employment of professionals is not available in the IHCP register and could therefore not be used as a selection criteria beforehand. For the purpose of this paper, only nurses that reported working in an academic or general hospital in the questionnaire, were included.

4.2.2 Measurement instruments

The questionnaires were constructed specifically for this study and were designed to be as similar as possible for reasons of comparability. A list of procedures was compiled by the researchers on the basis of discussions and interviews with medical nursing and legal experts (see Box 2). The list contains a combination of reserved and non-reserved risky and less risky procedures that occur in practice on a regular basis. Some procedures were not included in the questionnaires for all respondent groups, due to specialisation and efforts to minimise the length of the questionnaire.

Box 2 *Reserved and non-reserved risky procedures listed in the questionnaires for gynaecologists, internists and nurses*

Reserved procedures

- Intravenous injection (directly)
- Intramuscular injection
- Venipuncture
- Insertion of peripheral infusion
- Administration of medication via infusion
- Changing dosage on infusion pump
- Increasing dosage on oxytocin infusion pump*
- Removal of epidural catheter
- Insertion of nasogastric tube
- Bladder catheterisation (female)
- Bladder catheterisation (male)
- Suture**
- Perineotomy *
- Amniotomy *
- Vaginal examination during delivery*
- Birth of the placenta *
- Supervision of expulsion*

Non-reserved procedures

- Assessment of cardiotocogram*
- Assessment of electrocardiogram
- Assessment of the need for sedatives
- Assessment of a blood glucose level

**These procedures were only listed in the gynaecologists' questionnaire*

***These procedures were only listed in the nurses' questionnaire*

Physicians were asked whether and how many times they had experienced problems when giving orders to nurses for one of the listed procedures in the previous 12 months. Those who had experienced a problem were asked to give a description of the most recent problem that had occurred and the reason why this problem occurred. Nurses were asked the same questions for problems with orders which they had received from physicians. In addition all respondents were asked similar questions about refusals of orders. Nurses were also asked about orders that they had first contemplated refusing, but had eventually carried out (contemplated refusals). In addition a description was asked of the course of action taken after the refusal or the contemplated refusal. Although some refusals or contemplated refusals are seen as problems, this is not automatically the case, which is why they were addressed separately in the questionnaires.

Respondents were further asked to indicate the extent to which they considered it safe for a nurse to perform the listed procedures, on a 4-point scale (not at all; on the orders of a physician according to the conditions in the reserved procedures regulations; likewise but without the need for the possibility of supervision or intervention; and without an order). The study is descriptive, and only percentages and simple counts are presented.

4.3 Results

4.3.1 Response rates

Of all the questionnaires that were sent to the gynaecologists and internists, 9 (3 and 6, respectively) were undeliverable, due to change of address or retirement. Of the remaining 247 gynaecologists, 160 responded (65%), and after selection on employment status, 152 were included. Of the remaining 344 internists, 207 responded (60%), and after selection on employment status, 190 were included. Of the 3,200 questionnaires sent to nurses, 58 were undeliverable, due to change of address or retirement. Of the remaining 3,142 nurses, 2,233 responded (71%) and, after selection on employment in a hospital, 687 were included (under the assumption response patterns for different sectors are equal, 71%).

4.3.2 Incidence of problems, refusals and contemplated refusals

A total of 12% of the gynaecologists, 17% of the internists and 11% of the nurses had experienced one or more problems in the previous 12 months when giving (physicians) or receiving (nurses) orders for one of the listed reserved or non-reserved risky procedures (median 2, respectively 3 times). Over three quarters had not experienced any problems (76-83%), while 5-9% had not given or received orders for any of the listed procedures.(Table1)

Table 1 *Incidence of problems, refusals and contemplated refusals of orders for reserved and non-reserved procedures in the previous 12 months among gynaecologists, internists and nurses (percentages)*

	Gynaecologists	Internists	Nurses
	n=145	*n*=190	*n*=678
Problems			
▪ Yes (median no. of times)	12 (2)	17 (3)	11 (2)
▪ No, never any problems	83	76	79
▪ No, never given/received orders*	5	6	9
*Refusals***			
▪ Yes (median no. of times)	14 (2)	19 (3)	30 (2)
*Contemplated refusals****			
▪ Yes (median no. of times)			11 (1)

**Gynaecologists and internists were asked about orders given; nurses about orders received. If orders had never been given/received, the questions about refusals and contemplated refusals could be left unanswered.*

***Gynaecologists n=140, internists n=177, nurses n=606*

****Nurses n=597*

Of the gynaecologists and internists, 14% and 19%, respectively, indicated that their orders for such procedures to nurses had been refused at least once in the previous 12 months (median 2, respectively 3 times). Almost a third of the nurses (30%) indicated that they had refused orders for these procedures in the

previous 12 months (median 2x), while 11% indicated that they had contemplated refusing an order for these procedures at least once in that period (median 1x) (Table 1).

4.3.3 Most recent occurrence of a problem, refusal or contemplated refusal

4.3.3.1 Procedure for which orders were given or received

Table 2 presents the procedures for which orders were given or received in the most recent occurrence of a problem, refusal or contemplated refusal in the previous 12 months. A few examples of descriptions that were given by gynaecologists, internists and nurses are displayed in Box 3.

Box 3 *Examples of problems, refusals and contemplated refusals mentioned by gynaecologists, internists and nurses*

	Gynaecologists	*Internists*	*Nurses*
Problems	*Problem with performance* When a nurse received orders from a physician to perform a catheterisation of the bladder, there was a problem with the performance because the wrong route was taken.	*Unauthorised, not further specified* A nurse who received orders from the internist to administer medication via an intravenous injection (metocplamide) indicated she was not authorised to do so.	*Disagreement with the medication policy* A nurse received orders to administer a large dose of prednison intravenously while the result of tests should have been awaited.
Refusals	*Unauthorised because of institutional arrangements/protocols* Orders from a physician to administer medication intravenously (bolus heparine) were refused by a nurse because she was not authorised to do this, due to arrangements in the institution. The gynaecologist offered his apologies and subsequently administered the medication himself.	*Disagreement with the medication policy* Orders from an internist to administer cardiac medication via an intravenous injection were refused by a nurse, because she was afraid of the effects. The internist explained these effects were known and intended, and performed the intravenous injection himself	*Unauthorised because of lack of proficiency* A nurse did not feel competent enough to give an intramuscular injection, as ordered by a physician because it was a long time since she had last done this. In the end, she observed one of her colleagues giving the injection, in order to be able to do it herself the next time.
Contemplated refusals	*Not asked*	*Not asked*	*Disagreement with the medication policy* A nurse received orders to increase dosage on a morphine infusion pump, but contemplated refusing because in her opinion the prescribed dosage would hasten the patient's death unnecessarily. Eventually the nurse did increase the dosage.

Table 2 *Procedures mentioned by gynaecologists, internists and nurses, in which the most recent problem, refusal or contemplated refusal occurred in the last 12 months (absolute numbers (percentages))*

	Problems			Refusals			Contemplated refusals
Procedures	Gyn. *n*=17	Intern. *n*=32	Nurses *n*=72	Gyn. *n*=20	Intern. *n*=32	Nurses *n*=171	Nurses *n*=59
Reserved procedures							
▪ Bladder catheterisation (female)	5 (29)		1 (1)	1 (5)	1 (3)	4 (2)	1 (2)
▪ Insertion peripheral infusion	5 (29)	7 (22)	4 (6)	4 (20)	5 (16)	24 (14)	3 (5)
▪ Intravenous injections (directly)		8 (25)	21 (29)	6 (30)	13 (41)	59 (34)	11 (19)
▪ Administration of medication via infusion	3 (18)	4 (13)	5 (7)		5 (16)	5 (3)	4 (7)
▪ Intramuscular injections	2 (12)		2 (3)	1 (5)		12 (7)	2 (3)
▪ Bladder catheterisation (male)		4 (13)	3 (4)		1 (3)	8 (5)	3 (5)
▪ Increasing dosage on oxytocin infusion pump				1 (5)			
▪ Changing dosage on infusion pump		3 (9)	8 (11)			9 (5)	2 (3)
▪ Insertion of nasogastric tube		2 (6)	8 (11)		2 (6)	6 (3)	6 (10)
▪ Removal of epidural catheter	2 (12)		2 (3)	4(20)		10 (6)	3 (5)
▪ Venipuncture		1 (3)	1 (1)	2 (10)	2 (6)	3 (2)	1 (2)
▪ Other reserved procedures reported by respondents*			3 (4)	1 (5)		11 (7)	7 (12)
Non-reserved procedures							
▪ Assessment of the need for sedatives			3 (4)			1 (1)	1 (2)
▪ Assessment of an electrocardiogram (ECG)			2 (3)			1 (1)	1 (2)
▪ Administration of medication		3 (9)	8 (11)		1 (3)	12 (7)	11(19)
▪ Other non-reserved procedures reported by respondents**			1 (1)		2 (6)	6 (3)	3 (5)

**Drawing blood via infusion(3), dialysis (3), detubation (2), intubation (2), administration of medication via subclavia catheter (2), repositioning subclavia catheter (2), connecting epidural pump (1), removal of navel catheter (1), insertion of jugularis line (1), intra-uterine insemination (1), removal of jugularis catheter (1), removal of subclavia catheter(1), removal of ventricle drain (1), feeding via subclavia catheter (1), regulation of mechanical ventilation (1), removal of a balloon pump(1).*

***No medication (2), stopping medication(2),requesting blood tests (2), stopping bleeding (1), admission of a premature infant without supervision (1), irrigation of the bladder (1), irrigation of a tracheo stoma (1), repositioning of the wrist (1), preparation of ERCP(1).*

Table 3 *Reasons mentioned by gynaecologists, internists and nurses for the most recent problems, refusals or contemplated refusals in the previous 12 months (absolute numbers (percentages))*

	Problems			Refusals			Contemplated refusals
Reason	Gyn. *n*=16	Intern. *n*=30	Nurses *n*=71	Gyn. *n*=20	Intern. *n*=32	Nurses *n*=171	Nurses *n*=62
Nurse considered him/herself unauthorised, because of:							
▪ lack of proficiency	2 (13)	3 (10)	9 (13)	7 (35)	7 (22)	71 (41)	14 (23)
▪ institutional arrangements/protocols	4 (25)	3 (10)	14 (20)	4 (20)	9 (28)	24 (14)	5 (8)
▪ inappropriate orders			6 (9)		6 (19)	11 (6)	4 (6)
▪ not further specified		3 (10)		8 (40)		3 (2)	
Nurse disagreed with the:							
▪ medication policy	3 (19)	4 (13)	24 (34)		6 (19)	39 (23)	22 (35)
▪ reserved procedure	1 (6)		2 (3)		1 (3)	8 (5)	4 (6)
There was, or the nurses expected, a problem with the performance	7 (44)	9 (30)	9 (13)	1 (5)	1 (3)	4 (2)	6 (10)
There was, or the nurse expected, an undesired or unforeseen consequence		5 (17)	2 (3)		1 (3)	6 (3)	4 (6)
Other		3 (10)	5 (7)			5 (3)	3 (5)

For the gynaecologists the last problem most frequently concerned orders for bladder catheterisation and the insertion of a peripheral infusion (both 29%), and for the internists it was intravenous injections and the insertion of a peripheral infusion (25% respectively 22%).(Table 2) As for the internists, the most recent problem for nurses most frequently concerned orders for an intravenous injection (29%). For all respondents who had experienced a refusal in the previous 12 months, the most recent refusal most frequently concerned orders for an intravenous injection (30-41%), followed by orders for the insertion of a peripheral infusion (14-20%). Of the gynaecologists 20% also mentioned orders for the removal of an epidural catheter.

Of the nurses who had at least once contemplated refusing orders in the previous 12 months, 19% indicated that in the most recent case it concerned orders to give an intravenous injection, and for 10% of the nurses it concerned the insertion of a nasogastric tube. Although administration of medication was not listed in general terms in the questionnaire, 19% of the nurses also mentioned this.(Table 2)

4.3.3.2 Reason for the problem, refusal or contemplated refusal

Table 3 lists the reasons for the most recent occurrence in the previous 12 months of a problem, a refusal of orders, or a contemplated refusal of orders. The reasons for the problems that were most frequently mentioned by gynaecologists and internists were problems with the performance (44% and 30% respectively), such as inability to insert a peripheral infusion or the incorrect insertion of a catheter. The reason that was most frequently mentioned by the gynaecologists and internists for a refusal of orders was that the nurses themselves were of the opinion that they lacked the necessary authorisation for different reasons such as a lack of proficiency or institutional arrangements or protocols (95% and 69% respectively).

Just over one third of the nurses (34%) gave as reason for the most recent occurrence of a problem that they disagreed with the physician's medication policy (among other things, because of an incorrect dosage or because they did not think that the medication was necessary). This was also most frequently given as a reason by nurses for a contemplated refusal of an order in the most recent case (35%), and in 23% of the cases it was given as a reason for the most recent refusal. The reason that was most frequently given by the nurses for the most recent refusal of an order was that they were of the opinion that they did not have the required authorisation (63%), 41% of whom did not consider themselves proficient enough to perform the procedure adequately. In describing the most recent experienced problem, one nurse reported that a comatose patient had died because a nasogastric tube had entered the throat.

4.3.3.3 Course of action after refusal or contemplated refusal

The majority of the gynaecologists and internists (89% and 74% respectively) and just over a third of the nurses (35%) indicated that after the most recent refusal of orders in the previous 12 months the physician had eventually performed the procedure, or was asked to do so. Furthermore, 16% of the internists and 18% of the nurses indicated that the procedure was performed by another nurse or physician.

Over two thirds of the nurses (71%) said that after the most recent contemplated refusal they had either performed the procedure themselves after consultation, or together with the person who gave the orders or a colleague (Table 4).

4.3.4 Views on the safety of performance of reserved and non-reserved risky procedures by nurses

Table 5 presents the views of gynaecologists, internists and nurses with regard to the extent to which they considered it safe for the listed reserved and non-reserved procedures to be performed by nurses.

4.3.4.1 Reserved procedures for which nurses currently have no functional independence

With regard to the performance of reserved procedures for which nurses currently have *no* functional independence, over 80% of the gynaecologists were of the opinion that it is not safe for nurses to perform a perineotomy or an amniotomy, even if it is carried out on the orders of a physician according to the reserved procedures regulations (84% and 81% respectively). This also applied, according to 69% of the gynaecologists, to a vaginal examination during delivery, and approximately half of them were of the opinion that this also applied to delivery of the placenta and supervision of the expulsion (52% and 49% respectively).

Of the gynaecologists 73% and of the nurses 61% were of the opinion that the removal of an epidural catheter could safely be carried out by a nurse according to the reserved procedures regulations. Almost a quarter (24% and 22% respectively) of them thought that nurses should have functional independence with regard to this procedure. On the other hand, 12% of the gynaecologists and over one third of the nurses (35%) were of the opinion that this procedure could only be safely performed by a physician. According to 68% of the nurses, this also applied to sutures.

Table 4 *Course of action, according to gynaecologists, internists, and nurses, after the most recent refusal or contemplated refusal in the previous 12 months (absolute numbers (percentages))*

	Refusals			Contemplated Refusals
Course of action	Gynaecologists *n*=19	Internists *n*=31	Nurses *n*=155	Nurses *n*=58
Person who gave the order performed the procedure him/herself, or was asked to do so	17 (89)	23 (74)	55 (35)	2 (3)
Another nurse or physician was asked to perform the procedure		5 (16)	28 (18)	
Procedure was performed, but after consultation and/or together with the person who gave the order or a colleague	2 (11)	3 (10)	6 (4)	42 (71)
Procedure was not performed, person who gave the order was informed			20 (13)	6 (10)
Discussion with person who gave the orders or colleague/supervisor			39 (25)	5 (8)
Other*			7 (5)	3 (5)

**Among other things: order changed, protocols/manual implemented, training received for procedure*

Table 5 *Views of gynaecologists, internists and nurses on the extent to which it is safe for a nurse to perform certain procedures (horizontal percentages);*
** 1=Not safe, only to be performed by physician, 2=Safe, but orders from physician required, according to the reserved procedures regulations, 3 = Safe, as 2, but arrangement of supervision or intervention not required (functional independence), 4=Safe, no orders from physician required*

	Gynaecologists, *n*=150				Internists, *n*=190				Nurses, *n*=672			
Current legislation	**1*** *physician only*	**2** *on the orders of*	**3** *functional indep.*	**4** *no orders*	**1** *physician only*	**2** *on the orders of*	**3** *functional indep.*	**4** *no orders*	**1** *physician only*	**2** *on the orders of*	**3** *functional indep.*	**4** *no orders*
Reserved procedures without functional independence (=2)												
▪ Perineotomy	84	7	4	5								
▪ Amniotomy	81	10	5	4								
▪ Vaginal examination during delivery	69	22	5	5								
▪ Birth of the placenta	52	38	6	4								
▪ Supervision of expulsion	49	41	7	3								
▪ Removal of epidural catheter	12	49	24	16					35	39	22	5
▪ Suture									68	26	5	2
Reserved procedures with functional independence (=3)												
▪ Bladder catheterisation (female)	1	18	48	33	2	31	52	15	1	32	48	19
▪ Intramuscular injection	1	32	51	15					1	21	61	18
▪ Insertion of nasogastric tube					2	43	43	13	0.5	27	51	22
▪ Changing dosage on infusion pump					43	-	47	11	1	33	43	24
▪ Insertion of peripheral infusion	3	62	22	13	3	49	36	12	13	51	25	10
▪ Administration of medication via infusion	-	60	36	5	1	53	42	5	0.6	48	46	6
▪ Intravenous injection (directly)	19	59	16	6	18	59	21	3	24	53	20	3
▪ Increasing dosage on oxytocin infusion pump	3	58	29	10								
▪ Venipuncture	3	46	30	20	3	30	40	28	24	40	24	12
▪ Bladder catheterisation (male)					4	49	39	9	7	43	37	14
Non-reserved procedures (=4)												
▪ Assessment cardiotocogram	32	50	14	4								
▪ Assessment electrocardiogram									73	21	3	2
▪ Assessment need for sedatives									47	39	11	4
▪ Assessment blood glucose level									27	43	17	12

4.3.4.2 Reserved procedures for which nurses currently have functional independence

With regard to reserved procedures for which nurses currently have a functional independence, the majority considered that it was safe for nurses to perform the following procedures functionally independent: bladder catheterisation in females (48-52%), intramuscular injections (51-61%), the insertion of a nasogastric tube (43-51%) and changing dosage on an infusion pump (43-47%). With regard to the latter procedure, 43% of the internists were (also) of the opinion that this could only be safely performed by a physician, compared to 1% of the nurses. With regard to the other listed procedures, with the exception of internists in the case of venal puncture, the respondents most frequently considered that these procedures could be safely carried out by a nurse according to the reserved procedures regulations, but *not* with functional independence (40-62%). For all of the procedures in question, one or more respondents were of the opinion that they could be carried out without orders from a physician (3-33%).

4.3.4.3 Currently non-reserved procedures

With regard to the currently non-reserved procedures, a small majority of the gynaecologists (4%) were of the opinion that the assessment of a cardiotocogram could be safely carried out by nurses on their own initiative, without orders from a physician. Approximately one third (32%) thought that the assessment could only be safely performed by a physician, and half of the gynaecologists (50%) considered that it was safe if a nurse did this, but only on the orders of a physician according to the reserved procedures regulations (without functional independence).

In the opinion of 2-12% of the nurses, it was safe for nurses to assess an electrocardiogram, the need for sedatives and a blood glucose level on their own initiative, without orders from a physician. Almost three quarters of the nurses (73%) were of the opinion that an electrocardiogram could only be safely assessed by a physician. Almost half of the nurses (47%) had the same opinion about assessment of the need for a sedative. Most of the nurses (43%) considered that it was safe for nurses to assess a blood glucose level, as long as this occurred on the orders of a physician in accordance with the reserved procedures regulations (without functional independence).

4.4 Discussion

In the opinion of the authors, the data presented here give reliable insight into the occurrence of problems, refusals and contemplated refusals of orders for reserved and non-reserved risky procedures given to nurses by physicians, and

of their views concerning the extent to which it is safe for nurses to perform these procedures. We feel this Dutch data can provide relevant information for international readers too. The response was reasonable to good, and because anonymity was guaranteed we do not feel that problems, refusals and contemplated refusals were underreported. One limitation, however, is that the study only included questions on part of the risky procedures being performed in hospitals. Moreover, some respondents found the classification of problems, refusals and contemplated refusals difficult.

The results of this study show that, in practice, only a minority of physicians and nurses experience problems with regard to giving or receiving orders for reserved and non-reserved risky procedures. It also appears that orders are not often refused or contemplated to refuse. The problems mostly concerned orders for bladder catheterisation, the insertion of a peripheral infusion, and intravenous injections. Orders that were refused mainly concerned the insertion of a peripheral infusion and intravenous injections, and orders that were contemplated to refuse mainly concerned orders for intravenous injections and the insertion of a nasogastric tube. These are all reserved procedures that can currently be performed by nurses with functional independence, i.e. without the requirement of arrangement for supervision or the possibility of intervention.

Interpretation of the occurrence of problems, refusals and contemplated refusals in practice is somewhat ambiguous. On the one hand, problems, refusals and contemplated refusals can indicate errors and practical dilemmas, which occur because the task shift from physicians to nurses goes too far. On the other hand, they can be seen as a reflection of a well-functioning quality control and safety system, in which the nurses can raise the alarm. Moreover according to the reserved procedures regulations orders for reserved procedures should be refused when the nurse does not asses her proficiency as being sufficient to perform the procedure. A careful contemplation by individual nurses whether to accept or refuse an order is also in line with these regulations.

From this study it appears that the most recent experienced problems mainly concerned performance, in which an action was not successful or the wrong approach was taken. Although in one case a nurse reported that the patient had died, it is impossible to be sure that these problems would not have occurred even if the procedure had been performed by the physician. On the other hand, the occurrence of performance problems indicates that in a number of cases proficiency might not have been adequately assessed.

Orders were, in particular, refused when the nurses who had received the orders were of the opinion that they were not authorised, mainly because of a lack of the necessary proficiency, or when they disagreed with the medication

policy. Disagreement with the medication policy was also the most frequently mentioned reason for nurses to contemplate refusing orders.

The fact that nurses refused orders because they disagreed with the prescribed medication policy can imply that nurses are involved in work that in the Netherlands is currently restricted to the domain of the physician. The prescription of medication, whether or not by specialist nurses, as occurs in the UK and the USA, is not allowed in the Netherlands. Debate on this authorisation for specialist nurses has recently been initiated in the Netherlands.[7] Our data show that nurses assume their own individual responsibility with regard to medication policies. In a number of cases the nurse was of the opinion that the wrong medication or an incorrect dosage was prescribed for a patient. In the case when refusal of orders were considered the procedure was, indeed, performed, but when it was performed by the nurse in question, this was only after discussion, or together with the professional who had given the orders.

This study further shows that the views of the respondents do not entirely correspond with the legal requirements, with regard to the extent to which they considered it safe for reserved and non-reserved procedures to be performed by a nurse. With regard to certain procedures, the opinion of the professionals is more strict than the current legal regulations. According to the majority of the professionals, various procedures for which nurses currently have functional independence could not be safely performed in this way by a nurse. With regard to those procedures that are currently not reserved, i.e. assessment of an electrocardiogram, the need for sedatives, and a blood glucose level, only a small minority of the nurses were of the opinion that these procedures can be safely performed by nurses without orders from a physician.

Considering the number and nature of the problems, refusals and contemplated refusals, it would seem that there is no question of any serious dilemmas in daily practice with regard to the reserved procedures regulations. Professionals may in some cases be stricter in practice than these regulations require, following their views. At the same time, the tendency to shift the performance of tasks to a 'lower' level increases the risk that the actual proficiency to perform a procedure correctly is lacking in certain cases. Although legal regulations should cause no restrictions when the shifting of tasks is beneficial and safe, vigilance is also required to prevent excessive delegation. Institutions should also provide adequate safeguards for quality and safety, such as written guidelines or protocols describing the way in which proficiency is to be determined within the institution.

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5

Reserved and other risky procedures by nurses in home care

practices, policies and perspectives

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Abstract

Introduction
In the Netherlands a new Act (IHCP Act) came into force in 1997, opening up the practice of medicine. However, for the performance of so-called reserved procedures, specific conditions and requirements were stipulated. This study aims to provide an insight into the functioning of the reserved procedures regulations in primary care.

Method
Postal questionnaires were sent to all 116 home care organisations in the Netherlands and a sample of 3,200 nurses, of which nurses working in home care were included.

Results
Response rates were 71% for the nurses (n=202) and 63% for the home care organisations (n=64). At least once in the previous month 43-71% of the nurses performed intramuscular injections, subcutaneous injections and bladder catheterisations on the orders of a physician. In total 3-13% of the nurses also performed these procedures on their own initiative in that period. Proficiency to perform reserved procedures was assessed per procedure by 81% of the nurses. In total 92% of the home care organisations had developed written policies with regard to the reserved procedures regulations. Problems with and (contemplated) refusals of orders for reserved procedures in the previous 12 months were experienced by 4-16% of the nurses. Their views on the safety of performance of certain procedures were more strict than the current regulations.

Conclusion
Professionals and home care organisations have made serious attempts to convert the reserved procedures regulations into daily practice, although some elements of the regulations remain unclear. As the role of nurses becomes more independent in daily practice more guidance and information is needed to make them aware of the boundaries of this independence.

5.1 Introduction

The roles of physicians and nurses have been changing in recent years, with a shift of tasks traditionally carried out by physicians to nurses. This has been motivated by medical technical developments, economic considerations and capacity problems in health care. Other factors in this development are the experienced lack of flexibility in the involvement of various health care professionals, the further professionalisation of the nursing profession, and attempts to improve the career perspectives and job satisfaction of nurses.[1-5] However, there seems to be no clear consensus on the safety of shifting tasks traditionally done by physicians to other professionals.

In their review of studies on the possibilities for shifting part of physicians tasks Richardson et al[6] found estimates of the percentage of tasks of physicians that could be performed by other professionals safely ranging from 4 - 90%, although most studies ranged from 25 - 70%. The studies Richardson et al discussed were mostly conducted in primary care and involved specialised nurses and nurse practitioners.

In two randomised controlled trials conducted in 2000 in the United Kingdom, differences were found in the consultations provided by general practitioners, practice nurses and nurse practitioners. These studies showed that patients were more satisfied with consultations with the practice nurse as compared to consultations with the general practitioner for minor illnesses.[7] The same was true for consultations with nurse practitioners for patients requesting same day consultations for their symptoms or concerns.[8] Both studies also found that practice nurses and nurse practitioners consultations were longer than those provided by general practitioners. In addition patients reported that the nurse practitioners provided more information on their illnesses. Regarding the safety of the consultations the former study found no differences in health status outcome after two weeks. The latter found no differences for the resolution of symptoms and concerns, the number of prescriptions issued, investigations ordered, referrals to secondary care or re-attendances.

In a review of studies on the equivalency of care provided by nurse practitioners and general practitioners Horrocks et al[9] found similar results and concluded that although the included studies found little or no differences in health outcome between patients that had consulted a nurse practitioner rather than a general practitioner the studies had important limitations. Many of the studies lacked statistical power to detect rare but serious adverse events and many different health outcomes related to single consultations of minor illnesses were used.

In this paper we will focus on the performance of risky procedure by nurses in home care in Dutch primary care. A brief description of the organisa-

tion of primary care in the Netherlands is provided in Box 1.

Box 1 *Organisation of home care and general practice in Dutch Primary care*

Home Care Organisations
At the time of the study 116 home care organisations were active in the Netherlands, employing around 180.000 different professionals who provide home care. Home care in the Netherlands includes nursing care by district nurses, but also other elements of care such as domestic help or the provision of medical devices.

General practitioner
Is held responsible for the care of the patient in the home care situation, is the gatekeeper for specialist care, and gives orders for nursing care to district nurses via the home care organisations. Most home care organisations use standardised order forms for giving orders for nursing care. Approximately 8.000 general practitioners work in primary care. An average practice consists of 2100 patients per general practitioner.

The regulation of the professions in Dutch health care changed in 1997 when the Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG) came into force. This act basically allows everyone to provide individual health care, replacing the monopoly formerly held by physicians and permitting a shift of tasks to other professions. However, provisions are included in the Act to restrict the performance of certain procedures that will pose unacceptable health risks to patients if performed by insufficiently competent professionals. The performance of these so-called *reserved procedures* is restricted to two groups of professionals: those with direct authorisation (e.g. physicians), and those who may, under certain conditions, perform the procedures on the orders of professionals with direct authorisation (e.g. nurses). The categories of reserved procedures listed in the IHCP Act, and the conditions and requirements stipulated in the reserved procedures regulations are presented in Box 2.

The performance of medical procedures by nurses in the Netherlands had, formerly, never been legally authorised, but was informally regulated in the so-called *extended-arm-construction*, which was developed in jurisprudence from 1952 onwards.[10] In this theoretical construction a nurse performing a procedure was merely considered to be the extended arm of a physician, who held the authorisation. However, nurses' own responsibility was not acknowledged and this informal regulation led to an unclear division of responsibility and confusion regarding who was allowed to do what.[11,12] The reserved procedures regulations are aimed at clearing up such confusion. In addition it formalises the independent role of nurses in acknowledging their own responsibility with accepting and performance of orders for procedures. The interpretation and manner in which some aspects of the reserved procedures regulations should be

Box 2 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	*Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions:* 1. There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2. If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

converted in daily practice have, however, been left open by the legislator. For instance the manner in which to assess or determine the proficiency of nurses to properly perform a procedure for which an order is given is not explicitly described in the regulations. The interpretation and conversion of these regulations in daily practice may therefore give some problems in practice. In addition the regulations may facilitate nurses refusing orders given to them by physicians, which may not only lead to a more critical review of orders, but also to potential conflicts between nurses and physicians in daily practice.

Besides the IHCP Act, which stipulates requirements for individual professionals, another Act (the Health Care Institutions Quality Act, 1996) imposes demands on the management of care institutions, stating that they must ensure appropriate care is provided within the institution.[13,14] In response to the introduction of the reserved procedures regulations it can be expected from these demands that care institutions, such as home care organisations in primary care, will have developed policies for dealing with the performance of reserved procedures within their organisation.

5.2 Aims of the study

This study aims to provide insight into the functioning of new legislation on the performance of risky procedures in primary care, the so called reserved procedures. The study will focus on the way in which nurses in home care and the management of home care organisations have converted these reserved procedures regulations into policies and daily practice, and the extent of adherence

to these regulations. In addition the views of nurses in home care on the safety of performance of certain procedures in their daily practice will be studied.

5.3 Method

5.3.1 Design
A questionnaire study was conducted among nurses and home care organisations in the Netherlands from July to September 2001.

5.3.2 Sample
A random sample of 3,200 nurses was drawn from the Individual Health Care Professionals register (IHCP register, in Dutch, BIG register). Included in the sample were nurses who had been registered before January 2001, had no restrictions or clauses concerning their registration, were born after 1-1-1942, and were living in the Netherlands. This register contains no information on current employment, and could therefore not be used to select nurses working specific sectors. Nurses who reported working for a home care organisation in the questionnaire were included. See Box 3 for further information on the registration and education of nurses in the Netherlands. In addition to the nurses in home care, the Boards of Directors (or management) of all 116 home care organisations in the Netherlands were approached.

5.3.3 Data-collection
Anonymous postal questionnaires were sent to the home addresses of the sample of nurses and to all the home care organisations. The questionnaires were developed specifically for this study, and were reviewed in advance by medical, nursing, and legal experts. The questionnaire for the nurses contained questions on knowledge of the reserved procedures regulations, estimates of the frequency of performance of specific reserved procedures on the orders of a physician and on their own initiative, the manner in which their proficiency was determined, the manner in which orders for intramuscular injections and catheterisations of the bladder were received, the instructions received and the arrangements made for supervision or intervention, adherence to the institutional guidelines, and the occurrence and content of problems with or (contemplated) refusals of orders given for reserved procedures. In addition, they were asked to give their views on the safety of performance of certain procedures by nurses.

The questionnaire for the home care organisations questionnaire contained questions on written policies that had been developed concerning the reserved procedures regulations, views on the protection of patients, and dilemmas with regard to the reserved procedures in their organisation.

Box 3 *Registration and education of nurses in the Netherlands*

Registration
The title of nurse can be used only after registration in the IHCP register, the register of health care professionals. Registration in the IHCP register is linked to a disciplinary code as well as a description of nurses' field of expertise. Further qualifications after initial formal education (e.g. a specialisation or nurse practitioners masters degree) are not (yet) registered.

Field of expertise (IHCP Act)
- The performance of procedures in the field of observation, monitoring, nursing and care.
- The performance of procedures in individual health care on the orders of a physician, following the physicians diagnostic and therapeutic work.

Training
A 4 years formal education at a school of Higher Nursing education or an equivalent in-service training is required. In addition to educational requirements for nurses in EU guidelines (77/453, 1977), these include training on quality assurance and health law.

Nursing and midwifery
Nursing and midwifery in the Netherlands are distinct and separate professions, with different educational requirements and authorisations. When referring to nurses in the Dutch context midwives are not included.

Although there is a difference between written guidelines and protocols, these terms are frequently mistakenly used interchangeably in practice. Therefore, the two terms were combined in the phrasing of the questions, to prevent missing data due to misunderstanding. When reference is made to guidelines, this refers to guidelines and/or protocols.

5.3.4 Data-analysis
Percentages and simple counts are presented. In addition, for nurses performing reserved procedures on their own initiative, group differences for gender, age (<30, 30-45, and >45 years) and part-time (<36h) or full-time (≥ 36h) employment were analysed by applying logistic regression-analysis.

5.4 Results

5.4.1 Response rates
Of the 3,200 questionnaires sent to the nurses, 58 were unanswered due to change of address or retirement. Of the remaining 3,142 nurses, 2,233 responded (71%) and after selection 202 district nurses were included (under the assumption that the response patterns for nurses from different sectors are equal, 71%). Of the 116 questionnaires sent to the home care organisations, 15 were unanswered due to change of address or mergers. Of the remaining 101 organisations, 64 responded (63%).

5.4.2 Knowledge of the reserved procedures regulations

Of the nurses, 68% were aware that they were not allowed to perform reserved procedures on their own initiative, 87% knew that it was illegal for an unauthorised person to perform a reserved procedure, and 84% knew that the performance of reserved procedures without the required proficiency was illegal.

5.4.3 Frequency of reserved procedures and proficiency assessment

Of the nurses, 71% and 68%, respectively, estimated that they gave intramuscular or subcutaneous injections on the orders of a physician at least once a month, with a median of 5 and 10 times a month. At least once a month, on the orders of a physician, catheterisations of the bladder were performed by 43% of the nurses (median 2x), 4% inserted a peripheral infusion (median 6x) and 4% gave an intravenous injection (median 5x). Moreover, 3-13% indicated that they (also) performed these procedures on their own initiative, without receiving orders from a physician. Reserved procedures were not performed at all by 12% of the nurses**.** No significant differences were found for gender, part-time or full-time employment or age in the performance of these procedures by nurses on their own initiative.

Of the nurses who did perform reserved procedures, 81% indicated that they assessed their own proficiency per procedure, and 46% had a certificate of proficiency from the home care organisation for one or more reserved procedures (i.e. a certificate listing the procedures for which a professional is proficient), 40% assumed that they were proficient on the basis of their training and 39% on the basis of a guideline, 23% assessed their proficiency per patient, and 4% considered that assessment of their proficiency was the responsibility of the physician who gave the orders.

5.4.4 Manner in which orders were given

Table 1 shows that written orders for intramuscular injections or bladder catheterisations were always or usually received by 77% and 72% of the nurses respectively, 29% and 37%,respectively, always or usually received verbal orders followed by a written confirmation. Most nurses usually received one order for the multiple performances of these procedures (79% and 72% respectively), and 34% and 36% of the nurses respectively usually received orders via a protocol.

Of the nurses 4-15% indicated that when they received orders they always or usually received instructions for intramuscular injections or catheterisations of the bladder. For most nurses the arrangement for supervision or intervention was always or usually the availability of a physician at a distance (63% respectively 64%).

Table 1 *Manner in which nurses in home care received an order, types of orders received, instructions given and arrangements made for supervision and intervention when district nurses perform intramuscular injections or catheterisations of the bladder (percentages, more than one answer could be given)*

	Intramuscular injections *n*=129	Catheterisations of the bladder *n*=83
Way of receiving an order (always/usually)		
▪ In writing	77	72
▪ Verbally, with written confirmation	29	37
▪ Verbally, without written confirmation	3	4
Types of orders (usually)		
▪ One order for one specific performance	6	7
▪ One order for multiple performances	79	72
▪ Orders via a protocol	34	36
▪ Orders passed on from another nurse	19	21
▪ Orders delegated by a superior	8	7
▪ 'When necessary' or 'if .. then' orders	5	16
Instructions given (always/usually)		
▪ The method in general	15	13
▪ The method for this patient	6	4
▪ The possible complications and side-effects	14	13
Arrangements for supervision and intervention (always/usually)		
▪ Direct supervision in situ	14	23
▪ Physicial intervention if something goes wrong	21	13
▪ Availability at a distance	63	64
▪ Retrospective check	19	14

5.4.5 Institutional guidelines and adherence of nurses

According to 84% of the nurses, guidelines on reserved procedures were present in their home care organisation. According to the nurses these included a description of: 'the procedures for which the arrangement of possible supervision or intervention is not obligatory' (86%), 'the manner in which an order should be given'64%), 'the conditions for accepting an order' (56%), 'the way in which proficiency should be determined' (50%), 'the procedures that are reserved to be performed by physicians' (36%), 'the manner in which instructions should be given'(27%), 'the division of responsibility in giving and accepting orders'(29%) and 'the manner in which the possibility of supervision or intervention should be determined' (22%).

Furthermore, 71% indicated that they fully adhered to the institutional guidelines when performing reserved procedures, 26% adhered partially, and 3% did not adhere at all. The reason mentioned most frequently for not (fully) adhering was 'the situation of the patient' (57%). Other reasons included: 'the guidelines are not practical enough' (43%), 'I am not (fully) aware of the content of the guidelines' (28%), 'lack of time' (11%) and 'the guidelines are not formu-

lated/written clearly (4%).

5.4.6 Policies developed in the home care organisations

In total, 92% of the home care organisations had developed written policies with regard to the reserved procedures regulations: 93% had an educational and training policy, 76% had a written description of the reserved procedures that were performed within the organisation, 75% had a policy document, 61% had a special functionary or committee assigned to these policies, and 36% had a written review and adjustment policy with regard to the handling of reserved procedures.

All the organisations that had developed written policies had guidelines for reserved procedures, and 68% had developed these for all the reserved procedures performed within the organisation. Proficiency declarations for individual professionals were issued by 56% of the organisations, and 10% (also) issued these for groups of professionals, but 39% had no such declarations at all.

5.4.7 Problems, refusals and contemplated refusals of orders

Of the nurses 4% had experienced one or more problems in the previous 12 months when receiving orders to perform a reserved procedure listed in Table 3 (median 1x), 28% received no orders to perform these reserved procedures, and 68% had experienced no problems (Table 2).

Of the nurses who had received orders to perform reserved procedures in the previous 12 months, 16% had refused one or more of the orders (median 1x), and 11% indicated that they had contemplated refusing an order to perform these procedures at least once during that period (median 1x).

The majority of the most recently experienced problems concerned bladder catheterisation in male patients or injections (both 3x), the refusals and contemplated refusals mainly concerned orders for injections (7x and 5x, respectively). Lack of authorisation because of institutional arrangements or protocols, an (expected) problem with the performance or inappropriate orders were given most often as reason for the occurrence of a problem (all 2x), an inappropriate order was most often the reason for a refusal (5x), and for contemplated refusals both inappropriate orders and (expected) undesired and unforeseen consequences were the reasons that were most frequently given (both 5x).

Table 2 *Most recent problem, refusal and contemplated refusal of an order for a reserved procedure in the previous 12 months, according to procedure for which the order was given, the reason for the problem, refusal or contemplated refusal, and course of action after the refusal or contemplated refusal (absolute numbers)*

	Problems	Refusals	Contemplated refusals
	n=8	*n*=17	*n*=14
Procedures			
Injection	3	7	5
Bladder catheterisation (male)	3	2	2
Bladder catheterisation (female)	1		1
Catheterisation	1	2	
Administration of medication via infusion		4	3
Removal of an epidural catheter		1	
Insertion of peripheral infusion		1	
Replacement of a suprapubis catheter			2
Removal of a drain			1
Reasons[i]			
Nurse considered him/herself unauthorised, because of:			
▪ inappropriate orders	2	5	5
▪ lack of proficiency	1	4	4
▪ institutional arrangements/protocols		1	
There was, or the nurse expected, an undesired or unforeseen consequence	2	4	5
Other	2	3	
Course of action			
Person who gave the order performed the procedure him/herself, or was asked to do so		7	
Another nurse or physician was asked to perform the procedure		3	3
Procedure was performed, but after consultation and/or together with the person who gave the order or a colleague		2	9
Procedure was not performed, person who gave the order was informed		3	1
Discussion with person who gave the orders or colleague/supervisor		2	
Other			1

[1] *1 missing for problems*

5.4.8 Views of the nurses on the safety of the performance of certain procedures by nurses (Table 3)

5.4.8.1 Reserved procedures (no functional independence for nurses)

With regard to the removal of an epidural catheter and sutures, 42% and 30% of the nurses, respectively, were of the opinion that this could be carried out safely by a nurse according to the current regulation, 13% and 11%, respectively, were of the opinion that this could be carried out safely by a nurse with functional independence. However, 40% and 55% of the nurses (respectively) were of the opinion that these procedures could only be carried out safely by a physician.

Table 3 *Views of nurses on the extent to which it is safe for a nurse to perform certain procedures, n=199 (horizontal percentages);*
1=Not safe, only to be performed by physician, 2=Safe, but order from physician required, according to the reserved procedures regulations, 3 = Safe, as 2, but no arrangement for supervision or intervention required (functional independence), 4=Safe, no order from physician required

Current legislation:	**1** *Physician only*	**2** *on the orders of*	**3** *functional independence*	**4** *No orders*
Reserved procedures without functional independence(=2)				
▪ Removal of epidural catheter	40	42	13	5
▪ Sutures	55	30	11	4
Reserved procedures with functional independence (=3)				
▪ Intramuscular injection	0.5	23	58	19
▪ Insertion of nasogastric tube	1	39	47	13
▪ Bladder catheterisation (female)	0.5	41	45	14
▪ Administration of medication via infusion	1	58	37	4
▪ Bladder catheterisation (male)	6	51	36	8
▪ Changing dosage on infusion pump	2	56	35	7
▪ Venipuncture	41	43	13	2
▪ Insertion of peripheral infusion	29	58	11	2
▪ Intravenous injection (directly)	46	47	6	1
Non-reserved procedures (=4)				
▪ Assesment of blood glucose level	15	37	25	24
▪ Assesment of need for sedatives	47	34	10	9
▪ Assesment of electrocardiogram	72	17	5	5

5.4.8.2 Reserved procedures (functional independence for nurses)
For bladder catheterisation (female), intramuscular injection and insertion of a nasogastric tube it was mentioned most frequently that these could be safely carried out by a nurse according to the current regulation (45-58%). For the remaining listed procedures a majority of nurses most frequently mentioned that these could be carried out safely by a nurse according to the reserved procedures regulations, but without functional independence (43-58%). For intravenous injections, venipuncture and the insertion of a peripheral infusion 46%, 41% and 29%, respectively, was of the opinion these could only be carried out safely by a physician.

5.4.8.3 Non-reserved procedures
For the assessment of a blood glucose level, the need for sedatives and an electrocardiogram, 24%, 9% and 5%, respectively, were of the opinion that no orders from a physician were required for the safe performance of these procedures by a nurse. In contrast, 15%, 47% and 72% of the nurses, respectively, considered that these procedures could only be performed safely by a physician.

5.4.9 Views of home care organisations on the reserved procedures regulations
Of the home care organisations, 80% considered that the reserved procedures regulations provide patients with adequate protection. Twelve explanations were given, among other things that the regulations promoted the quality of care (e.g by education and review, protocolisation and the awareness among professionals of their own individual responsibilities.

Dilemmas concerning the reserved procedures regulations within their organisation were reported by 42% of the home care organisations, and 41 explanations were given. Most frequently mentioned were practical dilemmas in the division of responsibility and tasks between general practitioners and hospital specialists in giving orders to district nurses (10x). Other dilemmas concerned obtaining written orders from general practitioners (9x), determining and maintaining proficiency (8x), arrangements for supervision or intervention (7x) and various other problems (7x).

5.4 Discussion

In our opinion this study gives a reliable overview of the way in which nurses in home care and home care organisations in the Netherlands have converted new legislation concerning the performance of risky procedures by nurses into policies and practice in primary care. The response rates were high, and because anonymity was guaranteed we believe that the home care organisations and nurses responded honestly. However, one limitation of the study is that the results are based on self-report. No before-after comparison could be made, because the study was conducted after the IHCP Act came into force.

Although specific regulations and the organisation of primary care may differ in various countries, these results may also provide relevant information for professionals, managers and policymakers internationally. With regard to the involvement of different professionals for the care provided to patients in the home situation patient safety issues call for regulation of who is allowed to do what. Especially when considering certain procedures that entail risk to the patient when performed by professional with insufficient competence or proficiency. At the same time there is a need for a system that can be flexible when changes in the division of tasks between professionals are beneficial for the patients involved. Different choices can be made in the regulations of the professions that relate to these issues, ranging from regulation trough legislation to self regulation by professionals involved and their professional organisations.

These data from the Netherlands illustrate the way in which different professionals involved in care for the patient in the home care situation handle new requirements. In addition the data provide information on the implications

of changes in authorisation status of nurses in the performance of medical procedures for the interpretation of nurses role in providing care to patients.

The reserved procedures subcutaneous injections and intramuscular injections are performed by approximately two thirds of nurses in home care on a regular basis, for bladder catheterisations this concerns 40%. The insertion of a peripheral infusion and direct intravenous injections are performed only by a small minority of nurses. Strikingly, some nurses also perform these procedures on their own initiative, without the necessary orders from a physician, although this is not in accordance with the requirements stipulated in the reserved procedures regulations, and is punishable by law. This may in part be due to nurses' lack of knowledge about the limitations of the authorisation status of nurses in Dutch health care. Earlier research reported even higher percentages of nurses in Dutch hospitals acting on their own initiative in performing reserved procedures (17-53%).[15]

In cases in which orders were given for the reserved procedures intramuscular injections and bladder catheterisations it becomes clear that the one-to-one order structure, as assumed by the legislator, is not often the case in primary care. The various professionals involved in the care of the patient in the home care situation are seldom present at the same time, and orders are given to nurses via their home care organisations rather than directly by physicians. Most frequently orders were given once for multiple performances, followed by orders via a protocol. This last category raises some questions on what can still formally be seen as an order as required in the reserved procedures regulations. Some explicit exceptions have been stipulated in the Act for nurses working in ambulances where the presence of a physician is problematic, and where acting according to rigorous protocols is accepted as working under orders. In general, however, accepting a protocol as an order given by a physician implies a more independent role of nurses than intended in the regulations, including forms of diagnosis and assessing indications for treatment. Instructions were often not given with orders and the most frequently mentioned arrangement for supervision or intervention was the availability of a physician at a distance.

Problems , refusals and contemplated refusals of orders for reserved procedures are not often experienced in practice. When problems, refusals and contemplated refusals do occur, this is mainly because orders are not given in a correct manner, either not according to the reserved procedures regulations or breaching institutional agreements on the manner in which the orders should be given. With regard to contemplated refusals, this also included cases in which the nurses feared undesired or unforeseen consequences. The data illustrate that nurses are critical of the content and the manner in which these orders are given by physicians. The views of the nurses on the safety of performance of certain procedures were sometimes even more strict than stipulated in

the current regulations. It can be assumed this will lead to a further critical review by nurses of the orders they are willing to accept from physicians. Refusals do not seem to have led to frequent conflicts between physicians and nurses.

When considering the changing role of nurses, Bowler and Malik[16] argue that a distinction should be made between extension and expansion of nurses' role. They associate extension of the nurses role with adding on tasks to the nurses role that were traditionally exclusively part of the medical domain, whereas expansion refers to expanding towards becoming independent autonomous professionals. In the case of nurses in primary care their definition of expansion seems to relate more to nurse practitioners than to nurses in home care. There is also a difference in training, nurse practitioners have undergone further training, often at graduate level to work autonomously and in the United States and the United Kingdom they are authorised to make independent decisions about a patient diagnosis and treatment.[9] It is therefore difficult to generalise the findings of the studies on the safety of nurse practitioners expanded roles to district nurses performing medical tasks.

Following Bowler and Malik's description of changing roles of nurses our results indicate that the resulting role of some district nurses in Dutch primary care, at least for some procedures, has become an expanded role rather than an extended one. In some cases current practice breaches the requirements in the reserved procedures regulations and goes beyond the more independent formal position of nurses that was introduced with the IHCP Act. Discussions on the future role of nurses in the Dutch health care system are still ongoing, both in the political and professional arena. Recently, in response to several reports[4,17,18], a steering group for the modernisation of education and professions in health care was installed by the Dutch government to recommend desirable changes in current education, practice and legislation.[19] Recent discussions between government and parliament have focussed on extending the reserved procedures regulations to medical diagnosis and prescribing drugs. However this latter discussion is currently focussed primarily on possibilities for expanding the formal role of nurse practitioners, rather than that of nurses in home care.

Almost all home care organisations have developed policies with regard to the reserved procedures regulations, as can be expected from the requirements in the Health Care Institutions Quality Act. Declarations of proficiency are used in most home care organisations, mainly for individual professionals within the organisation. Most nurses determine their own proficiency per procedure, although just under half of them also use declarations of proficiency provided by the organisation. However, it is still unclear exactly how these organisations assess the proficiency of nurses, or how often this is re-assessed.

It should be noted that in the reserved procedures regulations proficiency is considered to be the result of both training and recent work experience, and can therefore differ over time and per patient. Although declarations of proficiency can serve as an aid for nurses in the assessment of their proficiency, the responsibility of accepting an order for a reserved procedure remains with the nurse, and will have to depend on individual self-assessment of proficiency for every new order.

Just over two thirds of the nurses fully adhered to the guidelines that were available in the home care organisation, while a third adhered only partially or not at all. The most frequently mentioned reason for non-adherence was the situation of the patient, although it is specifically stated that the reserved procedures regulations do not apply in emergency situations. Other reasons given by the nurses were that the guidelines that had been developed were not practical enough, or that they were not fully informed about the content of the guidelines. Further analysis of these guidelines could provide more insight into possible improvements in the quality and application of such guidelines in practice.

Most home care organisations consider that the reserved procedures regulations provide adequate protection for patients. At the same time, however, a minority of the home care organisations reported practical dilemmas concerning the reserved procedures regulations in their organisation. The division of responsibility for orders when both general practitioners and specialists in the hospitals are involved in the care provided for the patient at home was mentioned in this respect. In addition written orders were not always (easily) obtained from general practitioners. Although in order to ensure appropriate care it is understandable that home care organisations prefer written confirmation of orders by general practitioners, this is, strictly speaking, not mandatory in the reserved procedures regulations, because orders that are given only verbally are equally acceptable.

Four years after the introduction of the reserved procedures regulations, professionals and home care organisations seem to have made serious attempts to convert these regulations in daily practice. The conversion of these regulations in primary care is complicated however, because of the distance between general practitioners and nurses in home care and orders that are given via the home care organisations. This seems to have led to order structures in primary care that leave much independence for interpretation on the part of the nurse in home care. A minority of nurses act on their own initiative without any orders from a physician when performing reserved procedures, and (also) do not always follow institutional guidelines.

At the same time management of institutions have made policies that are stricter than the reserved regulations in some respects, for instance demanding

written confirmation of orders from physicians. For certain procedures the views of a majority of nurses on the safety of their performance are also more strict than is required in the reserved procedures regulations, presumably leading to a more critical review of accepting orders for these procedures.

Although the reserved procedures regulations were aimed at clearing up confusion about who is allowed to do what, and formalising the independent position of nurses, there still seems to be confusion about the legal boundaries of this role. As this role is becoming more independent in daily practice, more information and guidance is needed to make nurses aware of the legal boundaries of their independence. The institutions that employ nurses and professional associations will have to play a major role in this process.

The data illustrate that in some cases the independent role of nurses in practice has gone beyond the scope of the reserved procedures regulations. Patient safety considerations should be central in the debate on the development of the independence of nurses in home care in the performance of medical procedures.

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6

Shift of tasks from general practitioners to practice assistants

practices and views of general practitioners

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De Bie J, Cuperus-Bosma JM, Gevers JKM, van der Wal G. Shift of tasks from general practitioners to practice assistants practices and views of general practitioners

Abstract

Introduction
In the Netherlands the former monopoly of physicians was ended with the Individual Health Care Professions Act (IHCP Act) which came into force in 1997. However, provisions were included for the performance of certain risky procedures (*reserved procedures regulations*). The objective of the study was to evaluate the functioning of the reserved procedures regulations in general practice.

Method
Postal questionnaires were sent to a sample of 400 general practitioners in the Netherlands. Questions included current practice, views of the safety of practice assistants' performance of certain procedures, experienced problems and refusals and practical dilemmas with triage by practice assistants.

Results
In total 237 general practitioners responded (62%). Of them 93% gave orders to practice assistants for giving injections at least once a month, and 39% gave such orders for venipunctures. Most general practitioners determined the proficiency of practice assistants to perform reserved procedures only once, before giving any orders to a practice assistant (59%). Of the general practitioners who gave orders to give injections or perform venipunctures most did this because the practice assistant could do this equally well (93% respectively 71%). Problems with orders given to practice assistants for risky or reserved procedures were experienced by 8%, while 24% experienced practical problems with triage by practice assistants.

Conclusion
In general practice some tasks have been shifted to practice assistants. The requirements safeguarding this seem to be met in general practice. The professional general practitioners and practice assistants associations could possibly pay more attention to the need for a systematic and periodical re-assessment of practice assistants proficiency and the way in which adequate safeguards can be achieved for triage by practice assistants.

6.1 Introduction

Tasks that were traditionally performed by physicians are increasingly being carried out by other professionals with a lower level of education, mainly due to medical-technical developments, capacity problems, and economic considerations.[1-4] However, there is no clear consensus on which tasks can be safely shifted to other professionals such as nurses or practice assistants.[5] Although task shifts may in some cases be beneficial for the quality of the care provided, the safety of patients may be at risk when these shifts are primarily motivated by practical and economical considerations and the tasks are shifted to professionals with insufficient competence. The regulation of which professional is authorised to perform which procedure in health care results from these patient safety considerations. Internationally, various choices have been made with regard to such regulations, with different degrees of emphasis on self-regulation versus legislation.[6]

In the Netherlands a new Act came into force in 1997, the Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG). This Act enables task shifts from physicians to other professionals and replaced the former monopoly of physicians in the performance of medical procedures. However, provisions are included in the Act, to restrict the performance of certain procedures that would pose unacceptable health risks for patients when performed by professionals with insufficient professional competence. These so-called '*reserved procedures'* may only be performed by two groups of professionals: those with direct authorisation (e.g. general practitioners) and, under certain conditions, by other professionals (e.g. practice assistants) on the orders of those with direct authorisation. The categories of procedures that are reserved and the *reserved procedures regulations* are listed in Box 1.

In general practice, tasks are often shifted from the general practitioner to the practice assistant (in Dutch, doktersassistent). In the Netherlands the organisation of general practice is comparable to that in a number of other countries (e.g. Canada, Denmark and the UK). Practice assistants carry out reception tasks as well as medical tasks and triage.[7] Their educational backgrounds can differ, ranging from training on the job to completing a vocational training programme.[8] In addition to practice assistants several new professions in Dutch general practice have been developed, aimed primarily at assuming tasks in care for chronic patients and performing medical technical tasks. Specifically these professions are practice nurses and specialised general practice assistants, with either a nursing or practice assistant's background combined with additional specialised training. (in Dutch praktijk ondersteuners huisartsen or POH-VK en POH-DA)[1]. In this study, however, we will focus on practice assistants with an average educational background. The title of practice assis-

tant is, as yet, not legally protected, although the desirability of title protection has been discussed by professional general practitioner and practice assistant organisations prior to the introduction of the IHCP Act.[9]

Box 1 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions: 1. There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2. If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3. If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

When considering patient safety in general practice with regard to the shifting of tasks to practice assistants, attention should not only be paid to their performance of medical procedures, but also to the role of practice assistants in triage and mediating the access to general practitioners. A study in the United Kingdom comparing the safety and effectiveness of nurse telephone consultations in out of hours primary care with general practitioners telephone consultations showed triage could be done in a safe and effective manner.[10] The educational background and medical expertise of practice assistants is, however, different from that of practice nurses. Although triage by practice assistants entails certain risks, it was not included in the list of reserved procedures, which consists primarily of medical technical procedures. The debate on the safety of triage by practice assistants has been fuelled by several verdicts of the Health Care Disciplinary Board.[11-13] It became clear from these verdicts that general practitioners have a responsibility in assuring adequate safeguards, including clear instructions, when practice assistants perform triage, but that they cannot be held accountable for practice assistants who do not comply with such arrangements.

This study evaluates the functioning of the reserved procedures regulations in primary care and the manner in which these regulations are integrated in daily practice by general practitioners. In addition, the safety of the per-

formance of certain procedures by practice assistants, dilemmas experienced with triage by practice assistants and opinions on the reserved procedures regulations were studied from the perspective of general practitioners. This study was conducted as part of the evaluation of the IHCP Act. For the evaluation survey studies were conducted among different subgroups of physicians, nurses and management of health care institutions, including general practitioners. Although data from practice assistants may give additional information on this topic, this group of professionals were not included in the scope of the current study.

6.2 Method

6.2.1 Study population

Anonymous postal questionnaires were sent to a random sample of 400 general practitioners, drawn from a register of the Netherlands Institute for Health Services Research (in Dutch: NIVEL register). Included were those general practitioners who were born after 1-1-1937, and had at least been working as a general practitioner in the Netherlands since 1-1-2001.

6.2.2 Measurement instrument

The questionnaire was designed specifically for this study and was reviewed in advance by medical and legal experts, and experts from the Dutch Association of Practice Assistants. It contained questions on: the number of injections, venipunctures and sutures performed monthly by general practitioners by practice assistants on the orders of general practitioners; the way in which proficiency was determined; the reasons for and arrangements made for possible supervision or intervention when practice assistants were ordered to perform injections or venipunctures; opinions with regard to the safety of performance of certain reserved and non-reserved risky procedures that commonly occur in general practice by a practice assistants with an average experience; the problems and refusals that were experienced by general practitioners when giving orders to practice assistants for reserved procedures, and the practical dilemmas experienced in connection with triage by practice assistants.

6.2.3 Analysis

The study was mainly descriptive, and simple counts are presented. Subgroup analysis was also performed with chi-square and logistic regression analysis for general practitioners gender, single-handed or group practices, and part-time or full-time availability of practice assistants.

6.3 Results

6.3.1 Study population

Of the questionnaires, 8 were returned unanswered, due to change of address or retirement of the general practitioner. Of the remaining 392 general practitioners, 241 responded (62%). A further 4 were excluded because they were no longer working, resulting in a study population of 237 general practitioners, of whom 39% were working in a single-handed practice and 61% were working in a group practice (which is representative for the Netherlands, www.nivel.nl). In total, 43% of the general practitioners indicated that they employed at least (the equivalent of) one full-time practice assistant in their practice.

6.3.2 Number of reserved procedures and determination of proficiency

Of the general practitioners 97% gave injections themselves at least once a month (median 10x), and 93% (also) gave orders to practice assistants for giving injections at least once a month (median 15x). With regard to venipunctures, 57% of general practitioners performed these at least once a month (median 2x) , while 39% (also) gave orders to practice assistants for this procedure (median 5x); for sutures these percentages were 92% (median 5x) and 4% (median 1x) respectively.

Table 1 *Ways in which GPs determine the proficiency of PAs when giving them orders to perform reserved procedures (percentages)*

	n=230
▪ I assume the proficiency of the PA on the basis of the training completed	46
▪ I determine the proficiency of the PA to perform the procedure per procedure	46
▪ I determine the proficiency of the PA to perform the procedure per patient	19
▪ I determine once in advance the procedures for which the PAs I work with are proficient	59
▪ I determine periodically (e.g. once a year) for which procedures the PAs I work with are proficient	17
▪ I consider this to be the responsibility of the PA	13

The way in which general practitioners determined the proficiency of practice assistants to perform a given order is shown in Table 1. Most general practitioners determined this proficiency only once, before giving any orders to a practice assistant (59%). Just under half (also) mentioned that they assumed the proficiency of the practice assistant on the basis of their training or they determined this per procedure (both 46%). Of the general practitioners 19% mentioned that they determined the proficiency per patient, 17% that they

determined the proficiency periodically (e.g. once a year), and 13% considered this to be the responsibility of the practice assistant receiving the order.

6.3.3 Reasons for and arrangements for supervision and intervention concerning orders for injections and venipunctures

Almost all general practitioners who gave orders to give injections did this because the practice assistant could do this equally well (93%), while 71% (also) indicated being too busy to perform the procedure themselves, 47% because they did not consider giving injections to be a challenge and 9% considered the practice assistant to be more skilled in this procedure than themselves. To give orders for venipunctures these percentages were 67%, 72%, 48% and 16%, respectively. Of the general practitioners who gave orders to give injections, 74% stated that the possibilities for supervision and intervention when giving orders usually or always consisted of physical intervention if something went wrong, 71% (also) arranged this by being available at a distance, 18% by direct supervision in situ, and 10% performed a retrospective check. For venipunctures these percentages were 66%, 67%, 16% and 11%, respectively.

6.3.4 Experienced practicability and views on the reserved procedures regulations

Of the general practitioners 68% were of the opinion that the reserved procedures regulations with regard to giving orders were partially or totally practical, 8% did not find them practical and 24% were unsure. Over half of the general practitioners (53%) stated that the introduction of the reserved procedures regulations had made no difference with regard to their work, 44% were of the opinion that the regulations are closely linked to daily practice, and 21% that the regulations impose too many restrictions. In total, 76% of the general practitioners were of the opinion that the reserved procedures regulations provide adequate protection for the patient, and 46% considered the regulations to be an improvement on the previous legislation.

6.3.5 Problems with and refusals of orders given to practice assistants

Of the general practitioners 18 (8%) had experienced at least one problem in the previous 12 months when giving orders to a practice assistant for one of the procedures listed in Table 3. The most recent problem that occurred in the previous 12 month most frequently concerned orders that were given for cervix smears (5x), followed by orders given for injections (4x), venipunctures (3x) and desensitisation (2x). The most frequently mentioned reason concerned the (expected) problems with the performance of the procedure (12x). Some GPs mentioned an (expected) unforeseen or undesired consequence of the performed procedure (5x) (Table 2).

Of the general practitioners 4 (2%) had experienced at least one refusal in the previous 12 months when giving orders to practice assistants for the listed procedures. The most recent refusal of orders by practice assistants concerned orders for cervical smears, injections, venipunctures and syringing ears (all 1x); most frequently reported reason was that the practice assistant considered him or herself unauthorised because of lack of proficiency (3x). The course of action taken after all the mentioned refusals was that the procedure was performed by the general practitioner who gave the order.

Table 2 *Procedures and reasons mentioned by GPs for the most recent problems with or refusals of orders given to PAs in the previous 12 months (absolute numbers)*

	Problems *n*=18	Refusals *n*=4
Procedures		
▪ Cervical smears	5	1
▪ Injections	4	1
▪ Venipunctures	3	1
▪ Desensitisation	2	
▪ Sutures	1	
▪ Spirometry	1	
▪ Strapping ankles	1	
▪ Freezing warts	1	
▪ Syringing ears		1
Reasons		
▪ There was, or the PA expected, a problem with the performance	12	
▪ There was an undesired or unforeseen consequence	5	1
▪ The PA considered him/ herself unauthorised because of lack of proficiency	1	3

6.3.6 Views on the safety of procedures performed by practice assistants

Of the general practitioners 80% were of the opinion that inserting an IUD could only be performed safely by a physician.(Table 3) Half of the general practitioners (50%) were of the opinion that sutures could only be performed safely by a physician, and just under half (47%) thought that sutures could be performed safely by practice assistants, on the orders of a general practitioner, according to the requirements of the reserved procedures regulations. Of the general practitioners, 55% were of the opinion that desensitisation could be performed safely by practice assistants according to the reserved procedures regulations, while 36% thought that this could only be performed safely by general practitioners. According to 54% of the general practitioners allergy tests could be performed safely by a practice assistant according to the reserved procedures regulations. With regard to vaccinations, spirometry, cervical smears, assessment of the need for a consultation with a general practitioner and freezing warts, 23% to 37% of the general practitioners were of the opinion that

these procedures could be performed safely by practice assistants without orders from a physician.

Table 3 *Views of GPs concerning the extent to which it is safe for a PA to perform certain procedures, (n=236, horizontal percentages)*
**1=Not safe, only to be performed by physician, 2=Safe, but orders from physician required, according to the reserved procedures regulations, 3 = Safe, as 2, but arrangement of supervision or intervention not required (functional independence), 4=Safe, no orders from physician required*

	1* *physician only*	**2** *on the orders of*	**3** *functional independence*	**4** *no orders*
Reserved procedures				
▪ Vaccination (injection)	1	48	28	23
▪ Sutures	50	47	2	1
▪ Desensitisation	36	55	7	2
▪ Woundcleaning	18	40	25	17
▪ Venipuncture	17	51	23	10
Non-reserved procedures				
▪ Inserting an IUD	80	16	3	1
▪ Allergy test	21	54	18	8
▪ Cervical smear	5	44	28	24
▪ Spirometry	5	36	36	23
▪ Assesing the need for a consultation	3	39	22	36
▪ Freezing warts	2	27	34	37

6.3.7 Practical dilemmas concerning triage by practice assistants

Practical dilemmas concerning triage by practice assistants were experienced by 55 general practitioners (24%), 52 of whom gave one or more further explanation(s) (in total 61). They most frequently mentioned that triage was not accepted by the patients and also the practice assistants lacked the necessary knowledge, experience or training (both 16x). Of the general practitioners who experienced practical dilemmas 8 found triage difficult in general and 7 had been confronted with an incorrect assessment. General practitioners (also) mentioned lack of time and/or non-availability of the practice by phone (6x), difficulties due to changes in staff or understaffing (6x), the high workload of practice assistants due to triage (2x), and no time for consultation with the general practitioner(2x).

Of the 177 general practitioners (76%) who did not experience any dilemmas, 30 gave a further explanation (a total of 37 explanations). Most of these general practitioners stated that the practice assistant in question was highly skilled, well trained and/or experienced (16x), and others mentioned the protocols and possibilities of arrangements for consultation in their practice (10x).

Subgroup analysis showed that general practitioners working in a single handed practice as compared to general practitioners in a group practice experienced significantly more dilemmas concerning triage (OR=.326, P=.003),

corrected for gender of the general practitioner and part-time or full-time availability of the practice assistant.

6.4 Discussion

This chapter gives an extensive overview of the functioning of the reserved procedures regulations in general practice, the way in which general practitioners in the Netherlands have integrated new legislation concerning the performance of medical procedures into daily practice, and their views concerning the safety of the performance of reserved and non-reserved procedures by practice assistants and the reserved procedures regulations. Although the specific regulations and the organisation of general practice differ in various countries, these results may provide relevant information for professionals and policymakers internationally. The response rates were satisfactory, and the anonymity of the questionnaires is thought to diminish the social desirability of the answers given. No before/ after comparison could be made, because the study was carried out after the IHCP Act came into force.

With regard to current practice in primary care concerning the shift of tasks that were traditionally performed by general practitioners to practice assistants, our results show that almost all general practitioners gave orders to practice assistants to perform the reserved procedure of giving injections. A substantial minority (also) gave orders to practice assistants to perform venipunctures. Competence of the practice assistants to perform these procedures equally well or even better than the general practitioner was the main reason why general practitioners gave these orders to practice assistants. The arrangements for supervision and the possibility to intervene when practice assistants performed these procedure, as required in the reserved procedure regulations, mainly consisted of physical intervention by the general practitioner if something went wrong. This is easily arranged in general practice, because the general practitioner is usually present in the practice, and that is where the performance of procedures by practice assistants will mostly take place.

Although proficiency of the practice assistant was the main reason mentioned for giving orders to practice assistants, it is notable that only a minority of the general practitioners periodically re-assessed the proficiency of a practice assistant to perform specific procedures. Periodical re-assessment is important because the proficiency of a practice assistant is the result of both training and more recent work experience. In practice, because general practitioners often work with one or more assistants who are well known to them, the assessment of proficiency by both general practitioners and practice assistants is likely to take the form of an ongoing process. More systematic attention to the experi-

enced dilemmas concerning proficiency and the desirability of extra training might benefit the care provided by practice assistants. This could take place during the practice assistant's periodical job proficiency assessment.

The introduction of the reserved procedures regulations made no difference to their work, according to a small majority of general practitioners. It is possible that these general practitioner already took precautions similar to the requirements stated in these regulations. Although three quarters of the general practitioners were of the opinion that the regulations provided patients with sufficient protection, some general practitioners felt that the regulations put too many restrictions in their daily practice. We do not know however, whether these general practitioner felt that the requirements in the regulations are too strict, or that the regulations apply to too many procedures.

In daily practice very few problems and even fewer refusals of orders by practice assistants were experienced by the general practitioners. The problems mainly concerned the performance itself or unforeseen and undesired consequences of the performance, and most often occurred in connection with cervical smears or injections. Although the descriptions of the problems are not evidently highly problematic, some of these issues could be addressed if extra attention is paid to the performance of these procedures and their potential consequences when instructions are given to practice assistants or when they receive their initial or on the job training. The data also illustrates the increased number of practice assistants involved in performing medical technical tasks such as cervical smears and injections. This is corroborated by a Dutch study into the performance of procedures and illnesses in general practice, that was conducted at about the same period as this study. The survey among practice assistants that was conducted showed that when compared to 1987 in 2001 the percentage of practice assistants that perform certain medical technical tasks including cervical smears and injections had increased significantly.[14]

When practice assistants refused orders our data showed that this was mainly because they considered themselves unauthorised to perform the procedure because of lack of proficiency. This is in line with the requirements of the reserved procedures regulations and indicates that practice assistants are critical of their proficiency to perform these tasks.

Practical problems concerning triage by practice assistants were experienced by just under a quarter of the general practitioners. Although triage is not included in the reserved procedures regulations, general practitioners can be held responsible for mistakes made by practice assistants in triage when this is due to insufficient safeguards in the practice arrangements.[11-13] Practical problems concerning triage by practice assistants were caused by a lack of acceptance of this role by the patients, and because in some cases the practice assistants lacked the necessary training or did not have the appropriate ex-

perience to fulfil this role. The quality of triage by practice assistants can be negatively affected when patients do not accept this situation, especially if they are then reluctant to describe their symptoms. Providing patients with more information about the practical need for triage and the way in which practice assistants and general practitioners communicate about patient contacts could possibly reduce this reluctance. This is illustrated by a study in the Netherlands which showed that one year after the introduction of a cardiovascular risk detection and intervention program in general practice performed by practice assistants with additional training, only 3% of the patients reported having little confidence in the expertise of the practice assistants to provide such care.[15] Of a different order are problems that arise due to the practice assistants lack of training or experience. General practitioners have a responsibility in determining the proficiency of practice assistants to perform this role of triage, similar to the reserved procedures. Most general practitioners (80%) agree that they should be accountable for the triage role of the practice assistants.[9]

With regard to the views of general practitioners concerning the safety of the performance of reserved and non-reserved procedures by practice assistants, it appears that general practitioners are not always in agreement with the legislator. For some procedures, for instance inserting an IUD, they are more strict in their judgement, while a substantial minority of the general practitioners are of the opinion that vaccinations can be safely performed by practice assistants on their own initiative.

In general practice some tasks that were traditionally performed by general practitioners have been shifted to practice assistants. The requirements safeguarding this shift seem to be met: most general practitioners delegate tasks because they feel that the practice assistant they employ is competent, and supervision can be given in situ in most cases. No major problems seem to occur in daily practice, although some general practitioners experience practical problems concerning triage role by practice assistants. The professional general practitioners and practice assistants associations could possibly pay more attention to the need for a systematic and periodical re-assessment of practice assistants proficiency. More information and training for general practitioners concerning the way in which adequate safeguards can be achieved for triage by practice assistants could also be beneficial, e.g. through the use of protocolised medical decision cards or medical decision software. Patients' awareness of the need for triage and the importance of the role of the practice assistant in the functioning of the general practice may facilitate their acceptance of this role.

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7

Risky procedures

experiences and views of psychiatrists and views of management of mental health care institutions

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Abstract

Introduction
To evaluate the functioning of the reserved procedures regulations in the Netherlands, which are included in the Individual Health Care Professions Act (1997), the experiences and views of psychiatrists and the views of management of mental health care institutions were studied with regard to risky procedures in mental health care.

Method
Postal questionnaires were sent to all 105 mental health care institutions in the Netherlands and a random sample of 300 psychiatrists.

Results
Response rates were 60% for the psychiatrists, 67% for the psychiatric hospitals and 62% for the ambualtory care institutions. According to 32% of the psychiatrists there were procedures in mental health care that are not legally regulated, but are so risky that they should only be carried out by or on the orders of psychiatrists. Two thirds of the psychiatrists (66%) thought that psychotherapy should be classified as a reserved procedure. The majority of the psychiatrists (65%-96%) were of the opinion that assessment of the need for seclusion, treatment in a crisis situation and the termination of treatment can only be safely carried out by or on the orders of psychiatrists. Although 60% of the psychiatrists working in an institution had protocols, 72% were of the opinion that these guidelines were not, or partially satisfactory. Over two thirds of the institutions (69%) thought that the reserved procedures regulations provide adequate protection for patients.

Conclusion
More attention should be paid by legislators, institutions and professional organisations to risky procedures in mental health care, in particular in the field of diagnostics and therapeutic procedures.

7.1 Introduction

With regard to risky procedures in mental health care, reports in the literature mainly concern risk assessment of a patient's danger to him/herself (e.g. the danger of suicide) or to others.[1-4] Recently discussions on patient safety in psychiatry have focused on medication errors.[5-11] In 2003 a task force on patient safety of the American Psychiatric Association (APA) issued a report with recommendations on preventing medication errors and in addition on the safe use of seclusion and restraint and the prevention of suicide.[12] Another issue in patient safety in mental health care is the question which professionals can provide which part of the care in a responsible and safe way. This has, to our knowledge, not been empirically studied. There is, however, a certain amount of jurisprudence in this respect.(see Box 1) If only for practical reasons, some procedures traditionally part of the domain of physicians, will also be carried out by other health care professionals with a lower level of expertise. The way in which this is regulated to ensure sufficient patient safety differs per country, with more or less emphasis on legislation, jurisprudence and self-regulation by institutions and professionals.[13]

Box 1 *Dutch jurisprudence concerning the performance of procedures in the field of mental health care by others than physicians*

After the attending psychiatrist has been consulted, a patient who is voluntarily admitted is discharged from a psychiatric hospital. However, the patient leaves earlier than was agreed comes back again the evening before his official discharge date in an agitated state. On arrival he immediately wants to leave again. After the nurse on duty has found out where he is staying, she lets him go without consulting the psychiatrist. That evening the patient sets fire to a house. The owner of the house holds the hospital responsible for the damages. This claim is upheld by the Supreme Court.

Supreme Court, June 16, 2000.

A suicidal patient, who is voluntarily admitted, dies from suffocation with a plastic bag and an earphone cord. The Health Care Inspectorate files a complaint against the nurse in charge. Among other things, the complaint also states that for other attempts at suicide that evening the nurse did not follow the existing protocol and decided not to seclude the patient without consulting or receiving authorisation from the physician on duty. A sanction is imposed on the nurse by the Central Disciplinary Board for Health Care.

Central Disciplinary Board for Health Care, October 25, 2001.

A new Act was introduced in the Netherlands in 1997, the Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG). This Act opens up the practice of medicine, replacing the former monopoly of physicians in this field. At the same time certain provisions are included in the Act, restricting

the performance of procedures that will pose unacceptable health risks to patients if performed by individuals with insufficient professional competence. These procedures are called *reserved procedures*, because they may only be performed by two groups of professional practitioners: those with direct authorisation (e.g. physicians) and those who may, under certain conditions, perform a procedure on the orders of those with direct authorisation (e.g. nurses). The reserved procedures regulations are explained in more detail in Box 2.

Box 2 *The reserved procedures regulations in the Netherlands*

Reserved procedures	*Conditions*
▪ Surgical procedures ▪ Obstetric procedures ▪ Catheterisations and endoscopies* ▪ Punctures and injections* ▪ General anaesthetic ▪ Procedures involving the use of radioactive substances and ionising radiation ▪ Cardioversion ▪ Defibrillation ▪ Electroconvulsive therapy ▪ Lithotripsy ▪ Artificial insemination	Reserved procedures may only be carried out by those with direct authorisation (e.g. physicians) within their field of expertise, or by others (e.g. nurses) on the orders of those with direct authorisation under the following conditions: 1) There must be reasonable grounds for assuming the nurse is proficient enough to perform the procedure properly, as determined by both physician and nurse. 2) If necessary the physician has to give instructions to the nurse, and the nurse must follow these instructions. 3) If necessary, arrangements for supervision or the possibility of intervention must be provided by the physician. *In emergency situations the reserved procedures regulations are not applicable.* *For procedures marked with a * nurses have a functionally independent status, and condition 3 does not apply.*

However, the list of reserved procedures does not contain any procedures that occur in mental health care, with the exception of electroconvulsive therapy and injections. During the run-up to the introduction of the IHCP Act there was both parliamentary and general debate about the need to include psychotherapy in the list of reserved procedures, but because the concept of psychotherapy was considered to be difficult to define and demarcate, it was decided not to do so.[14] Some procedures in mental health care are subject to other acts. The Psychiatric Hospitals Compulsory Admission Act (in Dutch, BOPZ) stipulates that patients cannot be admitted and treated without giving consent; The Supply of Medicines Act (in Dutch, WOG) stipulates that only physicians are

authorised to write prescriptions for medication. Other potentially risky procedures in mental health care, such as assessing the need for (voluntary) admission to and discharge from a psychiatric hospital and psychotherapy, are, in principle, allowed to be carried out by any professional. Besides the professionals involved, management of mental health care institutions in the Netherlands also play a role in assuring the safety of patients, as they are obliged to assure adequate care is provided within their institution (Health Care Institutions Quality Act, 1996; in Dutch Kwaliteitswet Zorginstellingen, KZI).

A prerequisite of the IHCP Act is that its functioning must be evaluated five years after its introduction, and for this purpose research has been carried out among professionals and management of health care institutions. For this paper the results of research among psychiatrists and management of mental health care institutions are presented.

7.2 Method

7.2.1 Study population

Postal questionnaires were sent to the (boards of) directors or management of all 44 general psychiatric hospitals and 61 regional institutions for ambulatory mental health care (in Dutch: RIAGGs) in the Netherlands and a random sample of 300 psychiatrists (drawn from the Register of Individual Health Care Professionals, in Dutch BIG register) in the second half of 2001. Included in the sample were psychiatrists who were younger than 65 years (the usual age of retirement in the Netherlands) , were registered before January 2001 without restrictions or clauses concerning their registration, and were working and living in the Netherlands.

7.2.2 Measurement instrument

Psychiatrists were asked questions about risky procedures in mental health care in three different ways:

1) First they were asked in a partly open question whether there were procedures in mental health care that were so risky that they should only by carried out by or on the orders of psychiatrists. Those who gave a positive answer to this question could then indicate what these procedures were (max. 3 per psychiatrist), whether extra regulations were needed for these procedures and whether these procedures could be carried out safely by health care psychologists. Procedures that were already included in the reserved procedures regulations or regulated under other acts had to be excluded by the respondents.
2) Subsequently, the psychiatrists were asked to indicate (on a 4-point scale) the extent to which they considered it safe for certain specific procedures to

be performed by a health care psychologist, a sociopsychiatric nurse or a social worker. Psychiatrists who were working in an institution were then asked whether in the institution or on their ward there were any written guidelines or protocols for these procedures and, if so, whether these were satisfactory.

3) Finally, the psychiatrists were asked specifically whether psychotherapy should be considered as a reserved procedure.

The management of the institutions were asked the following questions:

1) First, just like the psychiatrists, they were asked whether there were any procedures in their institution that were not included in the reserved procedures regulations, but were so risky that they should only be performed by or on the orders of physicians and, if so, what these procedures were. They were then asked how these procedures were currently dealt with in their institution.
2) They were then asked whether the reserved procedures regulations were experienced in their institution as an instrument that provides adequate protection for the patients.

When reference is made in this paper to answers from general psychiatric hospitals or ambulatory care institutions, these are the answers given by the Board of directors or management of these institutions. The research is descriptive, and only percentages and simple counts are presented.

7.3 Results

7.3.1 Response

One of the questionnaires sent to the psychiatrists was undeliverable, due to change of address or retirement. Of the 299 remaining, 180 responded (60%). After selection on employment status, 175 psychiatrists were included. One of the questionnaires sent to the psychiatric hospitals was also undeliverable, probably due to an organisational change or a merge. Of the 43 remaining, 29 were returned (67%). Of the 61 questionnaires sent to the ambulatory care institutions, 9 were undeliverable due to an incorrect address, an organizational change or a merge. Of the 52 remaining, 32 were returned (62%).

7.3.2 Risky procedures mentioned by the psychiatrists

Of the psychiatrists, 32% was of the opinion that in the field of mental health care there were procedures that were not regulated in the reserved procedures regulations or in other acts, but were so risky that they should only be performed by or on the orders of psychiatrists. The rest was of the opinion that there were no such procedures (55%), or did not know whether there were such

procedures (13%).

In total 80 risky procedures were mentioned by the psychiatrists in this regard (10 different procedures). Half of these were psychiatric diagnostics (50%), and the other procedures that were mentioned included among other things: assessing the need for admission and/or termination of treatment (16%), psychotherapy (10%), somatic diagnostics (8%), formulation or amending of a treatment plan (6%) and assessing the need for treatment in a crisis situation (6%). For all the procedures mentioned, most of the psychiatrists were of the opinion that extra regulations were necessary (84%), 38% via the reserved procedures regulations and 46% via an institutional protocol (Table 1).

Table 1 *Risky procedures mentioned by the psychiatrists (n=160), which according to them should only be performed by or on the orders of psychiatrists, possible extra regulations needed (via reserved procedures regulations or via institutional protocols) and safety of performance by health care psychologists (absolute numbers (percentages))*

Procedures	Total	Extra regulations needed*			Safe if performed by H.C. psychologists**
		Yes, via res.proc. regulations	*Yes, via proto-col*	*No*	*No*
▪ Psychiatric diagnostics	40 (50)	15 (19)	17 (22)	7 (9)	32 (82)
▪ Assessing need for admission and/or termination of treatment	13 (16)	3 (5)	6 (10)	1 (2)	7 (100)
▪ Psychotherapy	8 (10)	7 (9)	1 (1)	- (-)	2 (25)
▪ Somatic diagnostics	6 (8)	1 (1)	4 (5)	1 (1)	5 (100)
▪ Formulating/amending treatment plan	5 (6)	1 (2)	3 (5)	- (-)	3 (75)
▪ Assessing need for treatment in crisis situation	5 (6)	2 (2)	3 (4)	- (-)	3 (60)
▪ Other	3 (4)	1 (1)	2 (3)	- (-)	1 (33)
Total	80 (100)	30 (39)	36 (50)	9 (12)	

**1 missing for psychiatric diagnostics, 3 missing for assessing need for admission and/or termination of treatment, 1 missing for formulating/amending treatment plan*

***Health care psychologist, 1 missing for psychiatric diagnostics, 6 missing for assessing need for admission and/or termination of treatment, 1 missing for somatic diagnostics and 1 missing for formulating/amending treatment plan*

With regard to psychotherapy, 7 of the 8 psychiatrists who had mentioned it were of the opinion that it should be included in the reserved procedures regulations. Six (also) considered that health care psychologists could safely per-

form psychotherapy on their own initiative. With regard to the other procedures, in all cases the majority of the psychiatrists who mentioned them were of the opinion that they could not be performed safely by health care psychologists on their own initiative (54%-83%) (Table 1).

7.3.3 Safety of performance of specific risky procedures

Table 2 shows that, with regard to the specific listed procedures psychiatrist were asked about, most of them (65%-96%) were of the opinion that assessing the need for seclusion, treatment in a crisis situation and termination of treatment can only be safely carried out by a psychiatrist or on the orders of a psychiatrist (according to the reserved procedures regulations, Box 2). With regard to individual psychotherapy and group therapy, 41% and 45% of the psychiatrists, respectively, were of the opinion that this could be performed safely by health care psychologists without an order from a psychiatrist. On the other hand, according to the majority of the psychiatrists, sociopsychiatric nurses or social workers could not perform these procedures safely on their own initiative, or on the orders of a psychiatrist according to the reserved procedures regulations (71% and 62%, respectively 69% and 61%). For social workers this also applied to assessing the need to consult a psychiatrist in a crisis situation and to do an intake (67% and 61%, respectively).

7.3.4 Guidelines with regard to the procedures mentioned

Of the psychiatrists working in an institution (n=141), 60% indicated that there were written guidelines or protocols in the institution or on their ward with regard to the procedures mentioned. According to just over a quarter of them, these guidelines or protocols were totally satisfactory (28%), over two thirds considered them to be partially satisfactory (70%), and according to 2% they were unsatisfactory.

The reasons that were most frequently given by the psychiatrists who were of the opinion that the guidelines were only partially satisfactory or unsatisfactory were: 'Not all situations and procedures can be described or demarcated in a protocol' (24%), 'Protocols are not always clear or well known among professionals' (16%) and 'Guidelines are still in the implementation or adaptation stage' (16%).

7.3.5 Psychotherapy as a reserved procedure

In answer to the question about whether psychotherapy should be considered as a reserved procedure, two thirds of the 171 psychiatrists (66%) were in

Table 2 *Views of psychiatrists on the extent to which it is safe for certain procedures to be performed by a health care psychologist, a sociopsychiatric nurse and/or a social worker (n=172, percentages)*
**1=Not safe, only to be performed by the physician, 2= Safe, if on the orders of a physician, according to the reserved procedures regulations, 3=Safe, as for 2, but arrangement for supervision and intervention not a prerequisite (functional independence), 4=Safe, no orders from a physician required*

	Health care psychologist				Sociopsychiatric nurse				Social worker			
	1* *Physician only*	**2** *On the orders of*	**3** *funct. independ-ence*	**4** *No orders*	**1** *Physician only*	**2** *On the orders of*	**3** *funct. independ-ence*	**4** *No orders*	**1** *Physician only*	**2** *On the orders of*	**3** *funct. independ-ence*	**4** *No orders*
▪ Assessing need to seclude patient	60	32	5	4	40	44	10	5	78	18	4	1
▪ Assessing need for treatment in crisis situa-tion	35	42	13	10	20	54	17	10	58	30	10	2
▪ Assessing termination of treatment	32	33	22	13	32	41	20	8	48	26	19	8
▪ Assessing need to consult psychiatrist in crises situation	13	39	15	34	4	42	17	37	36	31	11	22
▪ To do an intake	12	38	22	29	18	38	22	23	31	30	20	18
▪ Individual psychotherapy	5	26	27	41	42	29	19	10	44	25	20	11
▪ Group therapy	6	24	25	45	32	30	25	14	35	26	24	15

agreement, one quarter disagreed (25%) and 9% did not know. Of those who agreed, 50 gave an explanation (44%): 27 were of the opinion that psychotherapy should be a reserved procedure because specialist training is required to obtain the specific expertise that is needed, 12 because psychotherapy is a risky procedure, and 8 because accurate diagnostics are required for indication. Furthermore, one psychiatrist mentioned that the final responsibility lies with the psychiatrist, and that there is much uncertainty about what is and is not considered to be psychotherapy.

Of the psychiatrists who were of the opinion that psychotherapy should not be considered as a reserved procedure, 12 (29%) gave an explanation: 6 thought that the intake and indication for psychotherapy should be reserved, 4 were of the opinion that this could equally well be performed by a health care psychologist, and 2 considered that psychotherapy was difficult to define. From the explanations that were given by those who did not know whether psychotherapy should be a reserved procedure, it appeared that they did not know what a reserved procedure was, or what was meant by psychotherapy in the question.

7.3.6 Views of the management of mental health care institutions

Of the management of 29 general psychiatric hospitals and 32 ambulatory care institutions, 38% and 28%, respectively, indicated that certain procedures were performed in their institution which were not included in the reserved procedures regulations, but were so risky that they should only be performed by or on the orders of physicians, 59% and 63%, respectively indicated that this was not the case in their institution, and the rest (3% resp. 9%) did not know. The hospitals and ambulatory care institutions that were of the opinion that such procedures occurred in their institution mentioned a total of 22 procedures (8 different procedures), 6 of which were subject to other acts. The two other procedures were psychotherapy and assessment of suicide and danger criteria (both mentioned once). For these procedures the institutions had introduced extra regulations in the form of written guidelines or protocols. Assessment of suicide and danger criteria was currently dealt with as if it was a reserved procedure.

More than two thirds of the psychiatric hospitals (69%) considered the reserved procedures regulations to be an instrument that provides adequate protection for patients. Almost one quarter (24%) did not know, and 7% were of the opinion that the regulations do not provide enough protection. These percentages for the ambulatory care institutions were 56%, 34% and 9%, respectively. Among the explanations given by those that thought that the reserved procedures regulations provides adequate protection was that it is a good way to maintain high quality professional treatment and that the regulations provide

adequate protection in combination with other acts and regulations. Those that were of the opinion that the regulations did not provide adequate protection, or did not know, mentioned, among other things, that the protection does not only depend on the regulations, but also on how these are implemented.

7.2 Discussion

In our opinion, this study provides reliable insight into the experiences and views of psychiatrists and views of management of mental health care institutions regarding risky procedures. The response from psychiatrist and institutions was reasonable to good, and also because of the anonymity of the questionnaire we are convinced that the respondents gave their honest opinion. A limitation of this study is that it is not possible to present data on the actual risks patients are faced with when the described risky procedures are performed in mental health care by different professionals. Although the data presented represents the Dutch situation, we feel it also provides relevant information for practitioners and policymakers in other countries.

Our results show that, according to one third of the psychiatrists, in the mental health care sector there are procedures that are not included in the reserved procedures regulations or any other acts, but that are so risky that they should only be performed by or on the orders of psychiatrists. This concerned, in particular, psychiatric diagnostics and assessing the need for admission or termination of treatment. The majority of psychiatrists were of the opinion that for these procedures there should be extra regulations, via an institutional protocol or the reserved procedures regulations. Discussions on the need to include diagnostics in the reserved procedures regulations are still ongoing between Dutch government and parliament.

What is remarkable is that the psychiatrists were not consistent in their answers to the various questions about risky procedures in mental health care. When asked about the occurrence of procedures that are so risky that they should only be performed by or on the orders of psychiatrists, only a small minority mentioned psychotherapy. On the other hand, two thirds of the psychiatrists gave a positive answer to the specific question of whether psychotherapy should be included in the reserved procedures regulations. Apparently, when answering the first question, the psychiatrists did not automatically think about psychotherapy or did not consider psychotherapy to be one procedure. Perhaps this is because psychotherapy is a broad concept, which can entail many forms and variations of specific types of psychotherapy. Also some psychiatrists may consider psychotherapy to be potentially risky, but did not mention this as a potentially risky procedure because in daily practice they are more often involved in diagnostic and advisory tasks rather than in giving psy-

chotherapy. The most important reasons mentioned for including psychotherapy as a reserved procedure were the need for specific expertise, the risky character of psychotherapy and the need for accurate psychiatric diagnostics.

With regard to the extent to which it is safe for currently non-reserved procedures to be performed by health care psychologists, sociopsychiatric nurses or social workers, most of the psychiatrists were of the opinion that assessing the need for seclusion, treatment in a crisis situation and termination of the treatment can only be performed responsibly by or on the orders of psychiatrists, in accordance with the reserved procedures regulations. This shows that psychiatrists consider these to be risky procedures. These opinions are in line with the jurisprudence (see Box 1).

With regard to other procedures, it was noticeable that the psychiatrists differentiated between health care psychologists, on the one hand, and sociopsychiatric nurses and social workers on the other hand. Individual psychotherapy and group therapy could, according to many psychiatrists, be carried out safely by health care psychologists on their own initiative, but not by sociopsychiatric nurses or social workers. If professionals may perform procedures on their own initiative this also implies shifting the diagnostics and indication for the procedures to these professionals. Apparently, psychiatrists are of the opinion that health care psychologists are capable of performing certain procedures, but sociopsychiatric nurses and social workers are not.

Regulation of the performance of procedures in the field of mental health care can also take place via self-regulation, such as written guidelines and protocols in institutions. Although most of the psychiatrists who worked in an institution indicated that there were written guidelines in their institution or on their ward, almost three quarters were of the opinion that these were only partially satisfactory or unsatisfactory. Problems that were mentioned were, in particular, that not all situations and procedures can be formulated in guidelines or protocols, but also that these are still in the development stage or that the existing guidelines are not always clear or well known among the professionals. These professionals should be provided with more information about the guidelines.

Around a third of the management of mental health care institutions indicated there were procedures that occured in the institution that are not included in the reserved procedures regulations or subject to other acts, but are so risky that they should only be performed by or on the orders of physicians. However, when asked which procedures were meant, only two institutions mentioned a procedure that was not included in the reserved procedures regulations or subject to other acts. This may be due to a lack of knowledge among the management of mental health care institutions on the legislation that applies to the performance of procedures which occur within their institutions.

Psychiatrists mention more of such procedures, perhaps this is because not all problems experienced by psychiatrists are brought to the attention of the management.

In spite of the lack of procedures in the field of mental health care in the list of reserved procedures (with the exception of electroconvulsive therapy and injections), the majority of the institutions were of the opinion that the reserved procedures regulations provide adequate protection for patients.

In view of these results, it seems that more attention should be paid to risky procedures in the field of mental health care, especially with regard to diagnostics (indications) and therapeutic procedures, in order to protect the vulnerable group of patients in this care sector. Which professionals can safely perform these procedures requires not only the attention from legislators, in considering whether the performance of these procedures should be subject to legal regulations, but also from the management of institutions in formulating and effectively implementing written guidelines or protocols for these procedures, as well as the professional associations in providing professional codes. Whichever policy choices are made will , of course, also depend on the system of regulation for which countries have chosen.

7.5 References

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8

General Discussion

8.1 Introduction

In this general discussion the most important results of the various different studies will be summarized and discussed. First, the strengths and limitations of the present study will be described in paragraph 8.2. Subsequently the research questions will be answered and discussed in accordance with the results of the study in paragraphs 8.3 to 8.6, and some concluding remarks will be made with regard to the functioning of the reserved procedures regulations in paragraph 8.7. Finally, in paragraphs 8.8 and 8.9 implications for practice, policies and future research will be addressed.

8.1 Strengths and limitations of the study

This study provides empirically based insight into the functioning of the reserved procedures regulations in Dutch health care practice. For this study, large random samples of professionals and management of all general and academic hospitals, home care organisations, psychiatric hospitals and regional ambulatory institutions for mental health were approached. High to moderately high response rates were obtained, and the samples of professionals were found to be representative.[1]

The questionnaire mainly contained highly structured questions with the possibility to make remarks or give explanations where relevant. Although some of the questions can be considered to be of a sensitive nature, especially those related to experienced problems or dilemmas, anonymity was ensured to prevent under-reporting. In-depth interviews or observational studies might have provided more and different information, for instance on outcomes at patient level after nurses acted on their own initiative, or after problems were encountered in the performance of reserved procedures. However, because of time limitations and practical restrictions this was not possible within the scope of this study and would have resulted in a restriction in the size of the study group and extent of the settings.

The questionnaires were designed specifically for this study. They could not be formally validated, but to some extent the face validity and feasibility of the questionnaires was reviewed by various experts commenting on the content and phrasing of the questionnaire in several staged of their development. Medical, nursing and legal experts, both within and outside the research group were involved in this review. During the preparation of the questionnaires, interviews were also held with experts from various disciplines. In addition, editorial and opinionating articles on issues related to the reserved procedures regulations for the various professionals were scanned in order to identify possible missing issues in the questionnaires.

The study is mainly descriptive, and because no measurements were possible before the reserved procedures regulations came into force in the Netherlands, no effect analysis with either a before-after or a control group design could be made before or after these regulations came into force. It should be taken into account that the data were collected some 4 years ago. This is of importance because the situation with regard to the performance of tasks and procedures is continuously changing, possibly also affecting the applicability of some of the presented data to current practice. However, although some of the views concerning specific procedures might have changed in the meantime, the study gives a unique, valuable , and extensive description of the conversion of the legislation in practice and the perspectives of professionals and management.

8.3 Research questions

The main objective of the study was to provide empirically based insight into the functioning of the reserved procedures regulations in Dutch health care. The research questions that were addressed in this thesis were:

1) How have the reserved procedures regulations been converted in practice?
2) Which problems are experienced in daily practice with the reserved procedures regulations?
3) What are the perspectives of different professionals and management with regard to the safety of the performance of reserved and other risky procedures?

In the following sections these three research questions will be addressed on the basis of data from the various respondent groups from different health care sectors.

8.4 The reserved procedures regulations in practice (research question 1)

8.4.1 Performance of reserved procedures by nurses and practice assistants

The data show that, as expected, nurses and practice assistants were involved in the performance of reserved procedures in practice. In hospitals, most nurses performed reserved procedures on the orders of a physician on a regular basis. (Chapter 2) For the district nurses this was also the case for subcutaneous and intramuscular injections, but only a minority of them performed other reserved procedures on the orders of a physician on a regular basis. (Chapter 5) Almost all general practitioners gave orders to practice assistants for injections, while a substantial minority (also) gave orders to practice assistants to perform venipunctures.

A matter of concern with the delegation or shifting of tasks to other professionals is when this would be done solely on the basis of practical or economical reasons, rather than motivated by possibilities to improve the efficiency and quality of care.[2,3] However, in the case of delegated performance of reserved procedures this concern does not seem to be justified, because when giving such orders physicians take into consideration both the quality of the performance of the procedure by these professionals as well as their own time limitations. (Chapters 2,6)

Strikingly, a substantial number of nurses in hospitals and some nurses in home care also performed reserved procedures on their own initiative, without receiving orders from a physician. For the various reserved procedures this ranged from 17% to 53% of nurses in hospitals and 3% to 13% of nurses in home care. (Chapters 2,5) In these cases the nurses had transgressed the boundaries of their authorisation and had breached the requirements in the reserved procedures regulations. If nurses perform reserved procedures on their own initiative the decision when a procedure is indicated is shifted from the physician to the nurse, even though this is not included in the field of expertise or the formal education of nurses. It is worrying that nurses act on their own initiative in the case of reserved procedures, because the regulations were intended to protect patients against professional carelessness and incompetence and to ensure their safety in health care. With the exception of emergency situations, in which the reserved procedures regulations do not apply, this is, in fact, illegal and punishable by law. However, some caution is warranted in the interpretation of this data, because some nurses may have interpreted acting on the basis of a protocolised order as acting solely on their own initiative.

Lack of knowledge about the boundaries their authorisation may be an important factor in explaining why nurses act on their own initiative when performing reserved procedures outside of emergency situations. Only 43% tot 48% of gynaecologists and internists, and 63% to 68% of nurses in hospitals and nurses in home care were aware that nurses are not allowed to perform reserved procedures on their own initiative. (Chapters 2,5) Health care institutions in which nurses are employed should pay more specific attention to nurses who possibly act on their own initiative, and the circumstances within the institution that enable this to ensure that the appropriate care is still provided. Institutions are required to provide appropriate care, and should make sure that situations in which patients may be at risk and in which legal requirements are breached are avoided. Professional associations can also play an important role in improving the awareness of nurses with regard to the limits of their authorisation and possible consequences of their actions.

For individual professionals it may be beneficial if they are able to contact

a special functionary within the institution or from outside (i.e. through the professional associations) to help them with the interpretation of legislation in practice and to provide support in deciding when practice goes beyond the legal regulations. Paying repeated attention to orders and the authorisation of professionals in work-related meetings could also clear up confusion in this respect. A vigilant role of the Health Care Inspectorate towards cases that clearly transgress professional authorisation may be important to make clear which cases are not acceptable. The same holds for the disciplinary board. At the time of the study no single case resulting from a transgression of the reserved procedures regulations was put before a judge, in spite of the relevant legal provisions in the IHCP Act.[1]

8.4.2 Structure of orders for reserved procedures

The reserved procedures regulations are tailored to an assumed one-to-one relationship in the giving and receiving of one specific order for the performance of one specific reserved procedure. In general practice, for instance, arrangements for physical intervention and supervision can relatively easily be arranged when a general practitioner gives an order to a practice assistant. (Chapter 6) For nurses working in hospitals and in home care there is often no one-to-one relationship with the physician who gives the orders. The nurses reported that orders were given in more general terms ('if …then' orders), orders were given once for multiple performances, or were passed on from another nurse or via a protocol. Instructions on how to perform injections and catheterisations of the bladder were seldom given to nurses. Although for these procedures nurses have functional independence, instructions relating to specific circumstances of to specific patients may still be important. Arrangements supervision and the possibility of intervention often consisted of the availability of a physician at a distance. (Chapters 2,5)

The data show that, in practice, nurses mainly performed the reserved procedures for which they received orders independently. This raises questions about what can still be formally considered as acting on the orders of a physician, as required in the reserved procedures regulations. Accepting a protocol as an order given by a physician implies a more independent role for nurses than that intended in the current regulations, including types of diagnosis and assessing indications for treatment. The acceptance of more generic orders may be necessary to make up for the distance between professionals in practice, but an indication for treatment is a task that should not be shifted entirely to other professionals than physicians. A continuous critical review by both the professionals involved and the management of the institution is necessary in determining whether or not current practice goes too far in this respect, and in deciding when professionals are involved in work for which they are not suffi-

ciently qualified. In practice, nurses will have to play an important role in signalling such developments, and they should be critical about whether or not they are acting in response to a physicians' orders and are authorised to perform procedures in individual cases. As noted before, in order to be able to fulfil this signalling role the nurses should be more aware of the limits of their own authorisation, and support should be provided for individual professionals.

8.4.3 Determination of proficiency

Adequate proficiency of the professional who performs a reserved procedure is a central requirement in the reserved procedures regulations. However, the interpretation of proficiency and how it should be determined is mainly left open to the professionals involved. Most gynaecologists and internists assumed that the hospital had determined the proficiency of the nurses that it employed. Most hospitals and home care organisations did, in fact, work with some form of proficiency declaration (i.e. a certificate listing the procedures for which a professional is proficient), but approximately a quarter did not. (Chapters 3,5) Most nurses in hospitals and nurses in home care determined their own proficiency per procedure, and approximately half (also) based this on the certificates of proficiency provided by their institution. (Chapters 2,5) In general practice most general practitioners determine the proficiency of practice assistants to perform reserved procedures only once, before giving any orders for these procedures. (Chapter 6)

From this study it cannot be concluded how hospitals and home care organisations determine the proficiency of nurses, or whether this proficiency is systematically re-assessed. However, even if proficiency declarations issued by institutions are useful and valuable in helping professionals to determine proficiency, ultimately the professionals who give and receive orders for reserved procedures remain responsible for a critical review of proficiency in each individual case. Continuous and periodical attention paid to dilemmas concerning proficiency and the desirability of extra training, for instance during periodical job-proficiency assessments, might benefit the care that is provided by nurses and practice assistants. This is especially important because proficiency is not a static status, but is the result of both training and (recent) work experience.

8.4.4 Policies and institutional arrangements regarding reserved and other risky procedures

Although the reserved procedures regulations are aimed at individual professionals, as noted before, health care institutions also have an obligation to ensure that appropriate care is provided within their institution. It was expected that care institutions would make some efforts to ensure that the requirements in the regulations are met within the institution. A step-by-step plan to help

health care institutions develop policies on the reserved procedures was also distributed by the Ministry of Health after the introduction of the IHCP Act.[4] All hospitals and almost all home care organisations had indeed developed written policies with regard to the reserved procedures regulations. (Chapters 3,5) The policies developed by most hospitals and home care organisations mainly consisted of structural components, such as a policy statement, a description of the reserved procedures that were performed within the institution and the introduction of a functionary or committee specialised in the (development of) policies concerning the reserved procedures regulations. Almost all hospitals and all home care organisations that had developed policies had guidelines available for all or some of the reserved procedures performed within the institution. However, these were not always followed by a substantial minority of nurses, not only because of the individual situation of the patients, but in some cases also because they were not feasible or they were unclear. (Chapters 3,5)

It is noticeable that only a minority of the hospitals and home care organisations had developed a cyclic quality assurance system with regard to their policies on reserved procedures, although this would be more in line with the requirements for the management of care institutions in the Health Care Institutions Quality Act (CIQ Act 1996; in Dutch KZI).[5] This is especially important in keeping up to date with new developments and innovations in practice, and at the same time ensuring that appropriate care is guaranteed in institutions when involving professionals in the provision of care. The management of institutions can also play an important role in making the professionals working in their institution aware of their individual responsibilities and authorisations. Promoting a culture in the work environment of professionals that is focused on patient safety is an important task in this respect. This could be enhanced by providing individual professionals with support in the practical interpretation of legislation, and also by taking a cyclic approach to signals from the various departments and providing clear feedback on individual cases.

8.4.5 Perceptions of patient protection ensured by the reserved procedures regulations

A majority of the management of hospitals, home care organisations and mental health care institutions were of the opinion that the reserved procedures regulations provide sufficient protection for patients, ranging from 56% of the regional institution for ambulatory mental health care to 80% of the home care organisations. (Chapters 3,5,7) In the hospitals most of the respondents were of the opinion that the reserved procedures regulations provided patients with sufficient protection. (Chapter 2) Three quarters of the general practitioners agreed with this statement. (Chapter 5) Further research focused specifically

on patient outcomes and patient safety in relation to the performance of reserved procedures, may shed more light on whether or not these assumptions made by professionals and health care institutions are justified. Although this relationship could not be addressed directly in the current study, some inferences can be made on the basis of the data on the experienced dilemmas and the problems with and contemplated refusals of orders for reserved and other non-reserved risky procedures described in the following section.

8.5 Dilemmas experienced in daily practice (research question 2)

8.5.1 Practical dilemmas

Although most of the gynaecologists, internists and nurses in hospitals felt that the reserved procedures regulations were partially or totally feasible, some dilemmas in daily practice were reported. (Chapter 2) These included problems in obtaining written confirmation of verbal orders, in dealing with administrative 'red tape' and in determining the proficiency of nurses, and physical problems involved in providing supervision and intervention. Some of the dilemmas do not result from the requirements of the reserved procedure regulations, but from extra internal arrangements in institutions, such as obtaining written confirmation of verbal orders. In was also reported that in practice it was not always possible to adhere to the reserved procedures regulations because of the pressure of work, or a shortage of personnel, or because elements of the regulations were unclear. This is in accordance with the results of a study in which nurses working on gynaecological and obstetric wards indicated that they interpreted such practical dilemmas as emergency situations,[6] and in emergency situations the reserved procedure regulations do not apply. However, this exception to the reserved procedures regulations is only intended for emergencies in the patient's situation, and it does not apply to emergencies of a practical or organisational nature. In such cases, both the management of institutions and the professionals involved have a responsibility for finding solutions that do not compromise the quality of the care that is provided and do not breach the reserved procedures regulations. Just under half of the home care organisations (42%) reported practical dilemmas concerning the reserved procedures regulations, mainly with regard to the division of responsibility between general practitioners and hospital specialists when orders are given for a patient in the home care situation, and in obtaining written confirmation of orders given by physicians. (Chapter 5)

8.5.2 Triage by practice assistants

Approximately a quarter of the general practitioners experienced practical problems with triage by practice assistants, mainly caused by a lack of accep-

tance of this role by the patients, and because in some cases the practice assistants lacked the necessary training or did not have the appropriate experience to fulfil this role. (Chapter 6) Triage is not included in the reserved procedures, but can be considered as a risky procedure. There is some jurisprudence stating that general practitioners can be held accountable for mistakes made by practice assistants in triage when this is due to insufficient safeguards in the practice arrangements.[7,8,9] Most general practitioners agree that they should be accountable for the triage role of the practice assistants.[1] In general practice, clear arrangements should therefore be made with regard to triage.

A critical review of the practice assistants proficiency by both the general practitioner and the practice assistant, similar to the determination of proficiency for reserved procedures, is of critical importance to decide whether the practice assistant can safely perform this triage role. If necessary extra training or additional supervision should be provided. The use of decision aids can provide important support for practice assistants in this respect. Records of their contacts with patients and the advice given by practice assistants are important to enable general practitioners to perform retrospective checks, and could also be used as an aid in continuous monitoring of their performance with respect to triage. Practice assistants themselves should also be critical of the extent to which they are proficient enough to advise patients, and if in doubt they should always seek advice from the general practitioner or refer the patient directly to the general practitioner.

The lack of patients' acceptance of triage by practice assistants is in accordance with the results of a study on the acceptance of patients of Dutch primary care call centres (in Dutch: huisartsen post). In this study it was found that advice given by a practice assistant or nurse instead of a general practitioner was unacceptable to 52% of the patients, while 68% found it unacceptable if a practice assistant or practice nurse decided whether or not they could talk to a general practitioner.[1] When sufficient safeguards are put in place and the practice assistant's proficiency to perform triage is carefully considered, this apprehension may not be justified, although there is a need for more research taking into account patient outcomes after triage by practice assistants. The apprehension of patients with regard to the triage role of practice assistants could be reduced if they are provided with clear information about the practical need for triage, the way in which practice assistants and general practitioners communicate about patient contacts, possible decision aids that are used by practice assistants and the training of practice assistants. Uniform educational requirements for practice assistants, linked to title protection under the IHCP Act, could also clear up patient confusion about the background and competence of practice assistants.[1] Informing patients about the role of practice assistants and their training and background is not only of importance

in relation to triage, but also to their performance of reserved and non-reserved procedures in the practice. (see also 8.6.2)

8.5.3 Problems with and (contemplated) refusals of orders for reserved and non-reserved risky procedures

In practice, only a minority of physicians and nurses in hospitals and primary care had experienced problems in the previous 12 months with orders given or received for reserved and non-reserved risky procedures. Refusals of orders for such procedures were not experienced very often by gynaecologists and internists and only a small minority of general practitioners reported the refusal of orders by practice assistants. (Chapters 4-6) A third of nurses in hospitals and 16% of nurses in home care had refused orders for such procedures. Approximately 10% of nurses in hospitals and in home care had (also) contemplated refusing orders for such procedures, but had eventually carried out the procedures. (Chapters 4,5) The interpretation of problems with and (contemplated) refusals of orders is somewhat ambiguous. On the one hand they can indicate dilemmas and errors that occur, but on the other hand, they can be seen as a reflection of a well-functioning quality control and safety system, in which nurses or practice assistants can raise the alarm. Careful contemplation by nurses and practice assistants about whether or not to accept orders given to them by physicians is in line with the reserved procedures regulations.

The most recent problem experienced by physicians in hospitals and general practitioners most often concerned the performance of a procedure in which an action was unsuccessful or the wrong approach was taken. (Chapters 4,6) In some cases the proficiency of the nurse or practice assistant to perform this procedure may not have been assessed adequately. At the same time we cannot be sure that similar problems with the performance would not have occurred if the procedure had been performed by a physician. One nurse reported that a comatose patient had died when a nasogastric tube had entered the throat. (Chapter 4) However, to determine the patient outcomes and asses the severity of all the problems that were described, follow-up on the individual cases would be necessary.

Orders for reserved and non-reserved procedures were mainly refused by nurses in hospitals because of a lack of authorisation due to insufficient proficiency to perform the procedure, or because of institutional arrangements or protocols. (Chapter 4) District nurses mainly refused orders for procedures because inappropriate orders had been given. (Chapter 5) This illustrates a critical review and careful contemplation by nurses of the orders that they receive from physicians, which is in line with the requirements in the reserved procedures regulations. The fact that nurses critically review their own proficiency and authorisations is very important in the performance of reserved proce-

dures, and is, indeed, needed to ensure the quality of the care that is provided.

After a refusal, the most common course of action mentioned by gynaecologists, internists and general practitioners was that they themselves or another physician had eventually performed the procedure, or were asked to do so. (Chapters 4,6) Most nurses indicated that after their most recent refusal of an order the physician who gave the order or a colleague was asked to perform the procedure. After a contemplated refusal the procedures were performed, but only after consultation, together with the physician who gave the order or together with a colleague. (Chapters 4,5) With the introduction of the IHCP Act some concerns were expressed about possible conflicts between physicians and nurses over the refusals of orders and increased pressure on nurses to perform reserved procedures. However, our data provided no apparent evidence of frequent conflicts between physicians and nurses with regard to the refusal of orders or undue pressure on nurses to accept orders from physicians in their descriptions of the most recent problems, refusals or contemplated refusals. It is possible that conflicts may have been missed because no specific questions were asked about this in the survey. Qualitative research methods may be able to provide more in-depth information on the decision-making process that nurse and other professionals go through when deciding whether or not to accept orders from physicians for reserved procedures.

8.5.4 Nurses and medication policy

Nurses in hospitals most often experienced problems because they disagreed with the medication policy of the physician giving the orders. This was also most frequently the reason why they contemplated refusing an order. (Chapter 4) They seemed to assume their own responsibility with regard to the medication policy of the physicians; in some cases this concerned errors that they noticed by them, and, in other cases it concerned a difference of opinion with the physician with regard to the dosage or need for certain medication. The prescription of medication and medication policy decisions are currently exclusively restricted to physicians in the Netherlands under a different Act.[10] However, discussions about a more independent role of (specialised) nurses in this respect are ongoing.[11-13]

A special committee installed by the Ministry of Health to give advice on the modernisation of education and professions in health care (Steering group Modernisation Education and Professions in health care, in Dutch the MOBG) recently recommended that the prescription of medication should be included in the reserved procedures regulations to enable a shift of this task.[13] Although this recommendation was made by the MOBG in relation to new health care professionals in the Netherlands, specifically the professions of nurse practitioner and physician assistant, adding the prescription of medication to the list of

reserved procedures is an important departure from current practice, and would open up possibilities for the prescription of medication by specific groups of nurses. At the outset of this study specific questions about the prescription of medication were not included, because this is regulated under a different Act than the IHCP Act (The supply of Medicines Act). However, in light of the discussion on disagreement with the medication policy of physicians and recent discussions to include the prescription of medication to the list of reserved procedures, some exploratory discussion on its implication is of interest here.

Recently parliament has voted in favor of including the prescription of medication under the reserved procedures regulations. In addition it decided that specific groups of specialised nurses should have a direct authorisation to prescribe medication, under extra specified requirements, in addition to the other requirements of the reserved procedures regulations. A special ministerial decision is now in preparation to describe the details of this proposed amendment of the IHCP Act. The proficiency of the professional and the other requirements in the reserved procedures regulations would of course still have to be ensured when prescribing medication either independently or on the orders of physicians. For nurses, authorisation to prescribe medication is quite a step from assuming a responsibility for the administration of medication and critically reviewing orders for apparent mistakes. It implies indications and (work) diagnoses in order to be able to ascertain whether or not the right medications are prescribed. This goes beyond the current field of expertise of nurses that is defined as: '*observation, monitoring, nursing and care for patients and performing procedures in individual health care on the orders of a physician, following physicians diagnostic and therapeutic work*.' [16] Moreover the manner in which orders could be given for the prescription of medications is unclear.

In some countries, such as the UK nurse practitioners and physician assistants are allowed to prescribe medications.[2] Even further authorisation for nurses was recently announced in the UK, but some concerns were voiced about nurses prescribing medication beyond their competence, especially because there is a lack of rigorous peer reviewed research on the safety and appropriateness of nurses medication prescribing. More safeguards are recommended in this respect.[14]

Assuming that the prescription of medication would be included in the reserved procedures regulations, rigorous and regularly reviewed protocols for the prescription of medication, similar to those in ambulance care for instance, may be necessary. In addition the level of expertise of professionals involved in prescribing should be safeguarded trough specialised educational and training programmes. Other possible measures to assure patient safety may be limiting the type of medication that may be prescribed by other professionals, and rigorous screening of prescriptions for medications by physicians or pharmacists

before they are given out to patients. The recent discussion in Dutch parliament suggests that the ministerial decision should include protocolised working in the prescription of medication, the restriction to prescription of certain types of medication and the re-introduction of the final responsibility of the physician when nurses prescribe medication. This would involve a different approach to the authorisation of this specific reserved procedure, as compared to the other procedures already included in the list of reserved procedures.

Experiments with prescribing by nurses should be monitored, and the effects on patient safety should be compared with the effects of prescription by physicians. It should be kept in mind, however, that mistakes in prescriptions may also occur when done by physicians. A study on drug safety in Dutch hospitals concluded, for instance, that mistakes were made in approximately 10% of orders for medication and that mistakes were made in approximately one third of cases in which medication was administered in intensive care units.[15] However, regardless of who prescribes the medication, nurses have a joint role in the safety and quality system surrounding the individual patients who receive medication in a setting, such as in a hospital, where care is provided by different professionals.

8.6 Perspectives on the safety of performance of procedures (research question 3)

8.6.1 Safety of the performance of procedures by nurses

For some reserved procedures for which nurses do not have a functional independent status for nurses, a substantial number of respondents felt that these could only be safely performed by a physician. Most gynaecologists did not consider it safe for nurses to perform a perineotomy, amniotomy or vaginal examination during delivery on the orders of a physician. (Chapter 4) In a Dutch study on the desirability of future shifts in the tasks of nurses in hospitals vaginal examination during delivery was specifically mentioned.[3] However, our data show that most gynaecologists did not consider it safe for nurses to perform this procedure. Three quarters of the nurses in hospitals and just over half of the nurses in home care felt that sutures could only be safely performed by a physician, and one third, respectively 40%, of them felt that the same was true for the removal of an epidural catheter. (Chapters 4,5) The professionals are stricter in their opinions than the possibilities under the current requirements in the reserved procedures regulations. However, this does not necessarily indicate dilemmas with these procedures, but that professionals will not be inclined to give or accept orders for these procedures if they do not consider this safe.

For a number of reserved procedures for which nurses currently have a

functional independent status (no arrangements for supervision or intervention are obligatory), a substantial number of physicians in hospitals, nurses in hospitals and nurses in home care felt that these could only be performed safely if arrangements were made for supervision or intervention. This was, for instance, the case for insertion of a peripheral infusion, administration of medication via infusion, intravenous injections (directly) and bladder catheterisations in male patients. (Chapters 4,5) Although nurses have functional independence for the categories under which these procedures fall, if the professionals involved feel that for certain procedures it would be safer to make arrangements for supervision or intervention they should make such arrangements. In apparent contrast to the opinions of professionals, a quarter of the management of hospitals felt that nurses should have a functional independent status for more procedures than is currently the case. However, they mainly erroneously mentioned procedures for which nurses already had functional independence. This indicates a lack of knowledge about which procedures fall under which categories of reserved procedures, or for which categories nurses have a functional independent status. (Chapter 3) It is worrying that the management of health care institutions are apparently not entirely knowledgeable on this subject, especially in view of the demands that are made for them to provide appropriate care within the institution.

With regard to the safety of the performance of some non-reserved procedures, involving assessments and diagnostics the respondents were cautious. Most nurses in hospitals and home care felt that an ECG could only be safely assessed by a physician. Presumably, hospitals will also ensure that ECG are ultimately assessed by physicians. For the assessment of the need for sedatives and the assessment of a blood glucose level most nurses in hospitals and in home care felt that these could only be performed by a physician or on the orders of a physician, according to the reserved procedures regulations. (Chapters 4,5) The reserved procedures regulations mainly apply to medico-technical procedure, and some potentially risky procedures have not been included because they are difficult to define or demarcate. This is the case for diagnostic assessments and indications. Although these are not included in the reserved procedures regulations, the field of expertise of nurses is linked to their title protection and does not include such procedures and assessments. The problems involved in defining and demarcating such procedures clearly enough for them to be included in the reserved procedures regulations were reaffirmed by the Council of Public Health and Health Care in 2005.[16,17] Their advice on medical diagnosis was given to the Minister of Health following several reports including the Evaluation of the IHCP Act and two much publicised cases involving serious harm caused after patients received treatment by complementary or alternative health care providers. The council considered that too broad a defi-

nition would create unwanted limitations for other professionals in health care, and would conflict with the basic intention of the IHCP Act, i.e. to provide a balance between the freedom of choice for the patient/consumer and the patient protection. Instead of including medical diagnosis in the reserved procedures regulations, their advice was that patients should be better informed about what they can expect from professionals, and also that current possibilities in the IHCP Act for legal action, should be taken when such extreme cases do occur.

8.6.2 Safety of the performance of procedures by practice assistants

In the Netherlands, practice assistants have a central role in communication with and provision of care for patients in general practice. Our study shows that most general practitioners felt that practice assistants could safely perform several reserved procedures on the orders of a physician. These included venipunctures, desensitisation, vaccinations and woundcleaning. (Chapter 6) In their opinion about sutures the general practitioners were divided; half of them felt that only a physician could perform this procedure safely. Most general practitioners considered the non-reserved procedure of inserting an IUD was only safe if performed by a general practitioner. With regard to allergy tests, cervical smears, spirometry, assessing the need for a consultation, and freezing warts, most general practitioners felt that these could be performed safely by a practice assistant on the orders of a physician. (Chapter 6) The general practitioners were asked to assess the safety of the performance of a practice assistant with average training, but because there are no uniform requirements for the training of practice assistants and no legal title protection, their experience and competence can differ. (see also 8.5.2) In general practice, practice assistants can perform these procedure under supervision if necessary, and because general practitioners work with a limited number of practice assistants, proficiency assessments are simple.

8.6.3 Risky procedures in mental health care

With the exception of injections and electro-convulsive therapy, no procedures in the field of mental health care are included in the reserved procedures regulations. A third of the psychiatrist were of the opinion there were procedures in mental health care that are so risky they should only be performed by psychiatrist, or on their orders.(Chapter 7) This mainly applied to psychiatric diagnostics, and most psychiatrists felt that extra regulations were necessary, either via the reserved procedures regulations or via an institutional protocol. Diagnostics in all fields of individual health care are not explicitly restricted to physicians because of the earlier mentioned problems involved in definition and demarcation. However, the field of expertise of nurses is explicitly defined as

'following physicians diagnostic and therapeutic work'. Because of a lack of specific reserved procedures in mental health care, extra regulations, may be needed.

With regard to the extent to which it is safe for other professionals to perform specific procedures in mental health care, it becomes clear that most psychiatrists felt that assessment of the need for seclusion, treatment in a crises situation and the termination of treatment could only be safely performed by a psychiatrist, or on the orders of a psychiatrist (according to the reserved procedures regulations). Two thirds of the psychiatrists were of the opinion that psychotherapy should be considered for inclusion in the reserved procedures regulations. The main reasons that were given were that specialist training and expertise is needed for psychotherapy and that it is a risky procedure. However, a substantial minority of psychiatrists did feel that health care psychologists could safely provide individual and group therapy without any orders from a psychiatrist. (Chapter 7) Psychotherapy was not included in the reserved procedures regulations in the IHCP Act, because it was considered difficult to define and differentiate from other forms of patient counselling.[18]

Our data indicate that more regulation of procedures in mental health care may be needed to ensure that patients are sufficiently protected. This is especially important because procedures in mental health care can be invasive and can cause harm to patients. The possibility to include psychotherapy in the reserved procedures regulations, in spite of the problems with the definition and demarcation, should be further investigated. The professional associations of psychiatrist and health care psychologists could play an important role in this respect. However, although they play an important role in the protection of patients, the reserved procedure regulations do not exist in a vacuum and are not the only instrument that ensures the protection of patients. Management in mental health care institutions and the professionals involved should also be extra vigilant with regard to these procedures, and where needed extra regulations should be formulated within the institutions.

8.7 Concluding remarks on the functioning of the reserved procedures regulations

The functioning of the reserved procedures regulations in Dutch health care can be considered to be moderately positive. Most professionals and management of health care institutions were of the opinion that the regulations provide sufficient protection for patients and there was no evidence for large-scale occurrence of serious dilemmas in daily practice. However, in the conversion of the regulations in daily practice, not all the requirements are strictly met. Nurses assume a very independent and autonomous role, and mainly perform

reserved procedures independently. In some cases this is a breach of the reserved procedures regulations, especially when nurses act on their own initiative without orders from a physician. However, it is a positive sign that nurses are critical of the orders given to them by physicians.

The relationship between general practitioners and practice assistants is the most direct, and supervision and possibilities for intervention are, for instance, more easily arranged in general practice. Problems with and refusals of orders were not very common, but a quarter of the general practitioners did experience dilemmas with triage by practice assistants. This was mainly due to a lack of patient acceptance of the practice assistant's triage role and in some cases the educational requirements for triage were lacking.

Mental health care professionals felt a need for more regulation of the procedures, and critical attention to this aspect may also be a task for mental health care institutions. The perspectives of professionals in the all sectors was stricter for some procedures than the current regulations, presumably also resulting in a more critical review of the orders given for these procedures.

A continuous critical review of current practice and the safety of the performance of procedures that may cause harm to patients when performed by professionals with insufficient proficiency is necessary from the professionals involved, their professional associations and the management of health care institutions. When the regulations are clearly breached vigilant intervention by the management of health care institutions would is needed. Improvement of the knowledge of professionals and the management of health care institutions would help to clear up existing confusion about the boundaries of authorisation. Systematic attention paid to related issues, and the creation of a safety culture in the work environment, so that professionals and management are involved in ensuring the safety of patients is critical in this respect. If the management of institutions fail to ensure that the care that is provided is appropriate and safe, the Health Care Inspectorate may need to be more vigilant.

8.8 Implications for practice and policy

The knowledge of professionals and the management of institutions about the reserved procedures regulations and requirements needs to be improved. This is especially important with regard to the decision professionals are faced with when performing reserved procedures. Professionals need to receive clear orders for the performance of a procedure and need to know whether or not they are sufficiently proficient to perform a procedure, whether extra instructions are needed for them to be able to perform the procedure, and whether or not known arrangements are in place when supervision or intervention by a physician is needed. Most importantly, nurses and practice assistants need to be

made aware that performance of reserved procedures on their own initiative is illegal and that they must refuse any orders for which they are not proficient. This applies to all situations except emergencies, but professionals and institutions should be aware that emergency situations do not include practical problems such as a lack of personnel.

Professionals should be informed not only trough formal and continuous education, but possibilities for informational campaigns by the government or the professional associations should also be explored. Specific support for individual professionals and institutions may be required if they are in doubt about how to interpret legislation or cases in which orders given by a physician should be refused. This could, for instance, take the form of advice given by experts in the professional associations, and is especially important in view of ongoing developments in the field of health care.

The formation of the MOBG steering group is an important step in the further development of the professions. It should be noted that in the reserved procedures regulations authorisation to perform reserved procedures is not limited to a list of professions that are allowed to perform certain procedures. Training and specific work experience will create differences in competence and proficiency between professionals within the same profession and may result in similar competencies and proficiency to perform procedures between professionals of different background and profession. Following the reserved procedures regulations, when professionals, independent of their profession, are not sufficiently proficient to perform the procedure, they are not authorised to perform this procedure, regardless of their profession.

Experiments with authorisation will also have to follow this principle and should be accompanied by an evaluation of their effects on patient outcomes and the care process. As noted a differentiation should be made on the basis of considerable differences in training and work experience between nurses without extra training and nurse practitioners or specialised nurses with additional training, as well as other new professionals.

Although this study does not directly address the issue of the prescription of medication by nurses, some caution may be warranted with regard to the inclusion of the prescription of medication in the reserved procedures regulations. This is supported by the fact that in their assessment of certain procedures the professionals were stricter than the current requirements in the reserved procedures regulations. From this study it also became apparent that more attention should be paid to the regulation of procedures with regard to diagnosis and treatment in mental health care. If this is not possible under the IHCP Act, the institutions should take the responsibility to provide appropriate care.

Management of institutions also have an important role in ensuring that

all the professionals working in their institution are aware of the legal regulations that define the boundaries of their authorisation. Systematic and periodical attention to incidents concerning problems with performance and problems and refusal of orders may help to increase the awareness of patient safety issues. Paying continuous attention to aspects of patient safety in work-related meetings and providing support for individual professionals if they are in doubt about the performance of procedures may also stimulate a continuous critical review of daily practice. Management in institutions should also adopt an active approach in reviewing the manner in which reserved and other risky procedures are performed in their institution, and, if necessary, extra institutional arrangements should be made. This may be of special importance for mental health care institutions because of a lack of reserved procedures in this field.

8.9 Implications for future research

Further qualitative investigations of the reasons why nurses act on their own initiative may provide more in-depth insight into the decision-making process they go through when they are faced with professional responsibilities and independence in some respects, while still remaining within the legal boundaries of their authorisation. Similarly, a more qualitative approach to factors that inhibit or facilitate a critical review of orders given by physicians may provide further information in this respect. Experiments with new aspects of authorisation should be monitored, and their effects on patient outcome and process of care should be evaluated before they are implemented in daily practice on a large scale. Comparisons should be made with regard to the safety of the performance of procedures by physicians and other professionals to ensure that situations do not occur in which the safety of patients is compromised.

Large-scale evaluations of health care legislation, such as the evaluation of the Individual Health Care Professions Act, are an important tool to provide professionals, institutions and policy-makers with more information about how regulations have been converted in practice. In this manner the formulation of policies can be studied and the resulting empirical evidence can provide more insight into the aspects which might need extra attention in the implementation process. Part of the present study could be replicated to evaluate whether or not professionals and institutions have become more aware of the boundaries of professionals' authorisations and to determine the incidence of nurses acting on their own initiative when performing reserved procedures. Because various different developments are currently taking place with regard to the renewed registration of nurses in the IHCP register and the reserved procedures regulations, certain parts of this study could also be replicated after these changes have come into force.

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Summary

Reserved procedures in Dutch Health care: practice, policies and perspectives of physicians, nurses and management

This thesis describes a study into the practice, policies and perspectives of physicians, nurses and management of institutions with regard to the performance of reserved procedures and other risky procedures in Dutch hospitals, home care, general practice and mental health care. The postal questionnaires that provided the basis for this thesis originated from the evaluation of the Individual Health Care Professions Act (IHCP Act, in Dutch Wet op de beroepen in de individuele gezondheidszorg, Wet BIG)

In chapter 1 an introduction for the thesis is given and the background of the study, its objectives, respondents, and research questions are presented. Background of the study is the introduction in 1997 of a new system for the regulation of the professions in individual health care, with the Individual Health Care Professions Act. The purpose of this Act is to foster and monitor high standards of professional practice and to protect the patient against professional carelessness and incompetence. In the Act the freedom of choice for patients is assured by lifting the monopoly on the performance of medical procedures that was formerly held by physicians in the Netherlands. To guarantee sufficient patient safety at the same time, various provisions were included in the Act. In this thesis one of this provisions, the reserved procedures regulations, is studied.

The reserved procedures consist of 11 categories of procedures, including surgical procedures, obstetric procedures, catheterisations and endoscopies, punctures and injections. These categories of procedures were chosen because they could result in unacceptable health risks for patients if performed by people with insufficient professional competence. Reserved procedures may only be performed by professional practitioners with direct authorisation (e.g. physicians) within their field of expertise and, under certain conditions, by other professionals on the orders of these practitioners (e.g. nurses or practice assis-

tants). If the reserved procedures regulations are not adhered to, both of the professionals involved are punishable by law. (see also Box 1, e.g. page 12) The main objective of the study was to provide an empirically based insight into the functioning of the reserved procedures regulations in the Netherlands. The following research questions are addressed in the thesis:

1) How have the reserved procedures regulations been converted in practice?
2) Which problems are experienced in daily practice with the reserved procedures regulations?
3) What are the perspectives of different professionals and management with regard to the safety of the performance of reserved and other risky procedures?

Postal questionnaires were sent to all respondent groups. To include representative groups of professionals, random samples of nurses (n=3200), gynaecologists (n=250), internists (n=350) and psychiatrists (n=300) were drawn from the register of Individual Health Care Professionals (IHCP register; in Dutch the BIG-register). A random sample of 400 general practitioners was drawn from the NIVEL register of general practitioners. Response rates were 71%, 65%, 60%, 60% and 62%, respectively. All Boards of Directors or management of institutions of all 117 general and academic hospitals, 44 general psychiatric hospitals, 61 regional institutions for ambulatory mental health care (in Dutch the RIAGG) and 116 home care organisations in the Netherlands were approached. Response rate were 75%, 67%, 62 % and 63%, respectively.

In chapter 2 the knowledge of physicians and nurses working in Dutch hospitals concerning the reserved procedures regulations, their performance of such procedures, the manner in which orders are given and their views concerning the practicability and functioning of these regulations are presented. Almost all respondents were aware that physicians are authorised to perform reserved procedures on their own initiative (93-99%), and 48-63% knew that nurses are not authorised to do this. A substantial percentage of the nurses performed reserved procedures on their own initiative (17-53%). A majority of gynaecologists and internists presumed that the hospital had ensured the proficiency of the nurses to perform reserved procedures (58% resp. 65%), while 82% of the nurses determined their own proficiency for each procedure. Most respondents felt that the reserved procedures regulations offer adequate protection for patients (58-72%). In the Netherlands, the functioning of the mixed system, which includes the reserved procedures regulations in hospitals, can be considered to be moderately positive. To improve the link between legislation and practice, however, some changes are recommended, such as the acceptance of more ge-

neric orders where this does not compromise the safety of patients and where this does not imply shifting the entire process of deciding when a procedure is indicated to the domain of nurses. Further, confusion with regard to the determination of proficiency may be cleared up when the hospital management plays a greater role in this process. Finally, since knowledge can be seen as a prerequisite for compliance with regulations, more education during training and further dissemination of information to qualified nurses and physicians is necessary to make them aware of the current regulations governing the performance of certain procedures in daily practice.

Chapter 3 focuses on the policies concerning the reserved procedures regulations that were developed in hospitals, the views of the management of hospitals with regard to the reserved procedures regulations, and the adherence of nurses to the guidelines that were available to them. All hospitals had some form of policy on the reserved procedures regulations; a minority (41%) had a review and adjustment policy regarding the handling of reserved procedures. This is in line with our expectations, as hospitals have a responsibility in providing appropriate care, as formulated in the CIQ Act. Most hospitals have developed structural components of policy related to the reserved procedures regulations, such as a policy statement, a description of the present reserved procedures and a functionary or committee specialised in the (development of) policies on the reserved procedures regulations in the hospital. It is notable that despite the demands of the CIQ Act for a quality assurance system only a minority of the hospitals had developed a review and adjustment policy for dealing with reserved procedures. Therefore (further) promotion of review and adjustment is essential to keep policies and guidelines up-to-date.

Of the nurses 61% fully adhered to institutional guidelines when performing reserved procedures, 39% adhered partially (2 nurses indicated not adhering at all). Main reason for not doing so was the situation of the patient, although in emergency situations the requirements in the reserved procedures regulations may not apply. The reason most frequently mentioned for non-adherence was the situation of the patient (75%). Of the hospitals 71% considered the reserved procedures regulations to provide patients with adequate protection. In conclusion, it appears that the reserved procedures regulations, have resulted in hospital policies and guidelines on the reserved procedures regulations and are seen to contribute to quality of care and the protection of patients in hospitals. Nevertheless recommendations for improvement are made.

Chapter 4 discusses dilemmas that can occur in daily practice when specific reserved and non-reserved procedures are performed by nurses in hospitals. Of

the respondents 11-30% experienced problems with and (contemplated) refusals of orders for risky procedures in the previous 12 months. Gynaecologists and internists most frequently mentioned problems concerning the practical performance of the procedure (44% and 30% respectively). The reason for a problem or a contemplated refusal most frequently given by nurses was that they disagreed with the medication policy (34% and 35% respectively). The reason for a refusal most frequently given by the gynaecologists, internists and nurses was that the nurses themselves were of the opinion that they did not have the necessary authorisation (95%, 67%, and 62% respectively).

In practice, only a minority of physicians and nurses experience problems with regard to giving or receiving orders for reserved and non-reserved risky procedures. Interpretation of the occurrence of problems, refusals and contemplated refusals in practice is somewhat ambiguous. On the one hand, problems, refusals and contemplated refusals can indicate errors and practical dilemmas, which occur because the task shift from physicians to nurses goes too far. On the other hand, they can be seen as a reflection of a well-functioning quality control and safety system, in which the nurses can raise the alarm. Moreover according to the reserved procedures regulations orders for reserved procedures should be refused when the nurse does not asses her proficiency as being sufficient to perform the procedure. A careful contemplation by individual nurses whether to accept or refuse an order is also in line with these regulations. Considering the nature and number of problems, refusals and contemplated refusals this study does not provide evidence for serious dilemmas in daily practice in hospitals. Recommendations are made for institutions to provide adequate safeguards for quality and safety, such as written guidelines or protocols describing the way in which proficiency is to be determined within the institution.

Chapter 5 describes the practice and views of nurses in home care and home care organisations concerning the reserved procedures regulations, policies and guidelines for these procedures, and dilemmas that occur in the performance of reserved and non-reserved procedures. At least once in the previous month 43-71% of the nurses performed intramuscular injections, subcutaneous injections and bladder catheterisations on the orders of a physician. In total 3-13% of the nurses also performed these procedures on their own initiative in that period, although this is not in accordance with the requirements stipulated in the reserved procedures regulations, and is punishable by law.

According to 84% of the nurses guidelines for reserved procedures were present in their home care organisation, 71% fully adhered to these. In total 92% of the home care organisations had developed written policies with regard to the reserved procedures regulations. Problems with and (contemplated) refusals of orders for reserved procedures in the previous 12 months were experi-

enced by 4-16% of the nurses. Although practical dilemmas were experienced by 42% of the home care organisations, 80% considered the regulations provide patients with adequate protection. Considering the number and nature of the problems, refusals and contemplated refusals, it would seem that there is no question of any serious dilemmas in daily practice with regard to the reserved procedures regulations. Although legal regulations should cause no restrictions when the shifting of tasks is beneficial and safe, vigilance is also required to prevent excessive delegation. Institutions should also provide adequate safeguards for quality and safety, such as written guidelines or protocols describing the way in which proficiency is to be determined within the institution. Although the reserved procedures regulations were aimed at clearing up confusion about who is allowed to do what, and formalising the independent position of nurses, there still seems to be confusion about the legal boundaries of this role. As this role is becoming more independent in daily practice, more information and guidance is needed to make nurses aware of the legal boundaries of their independence.

Chapter 6 examines practices with regard to the performance of reserved and non-reserved procedures by practice assistants in general practice, experienced dilemmas and the perspectives of general practitioners on the safety of performance of specific procedures by practice assistants. Of the general practitioners 93% gave orders to practice assistants for giving injections at least once a month, and 39% gave such orders for venipunctures. Most general practitioners determined the proficiency of practice assistants to perform reserved procedures only once, before giving any orders to a practice assistant (59%). Of the general practitioners who gave orders to give injections or perform venipunctures most did this because the practice assistant could do this equally well (93% respectively 71%). Problems with orders given to practice assistants for risky or reserved procedures were experienced by 8%, while 24% experienced practical problems with triage by practice assistants. In general practice some tasks that were traditionally performed by general practitioners have been shifted to practice assistants. The requirements safeguarding this shift seem to be met: most general practitioners delegate tasks because they feel that the practice assistant they employ is competent, and supervision can be given in situ in most cases. More attention to the need for a systematic and periodical re-assessment of practice assistants proficiency and safeguards for triage by the professional general practitioners and practice assistants associations is recommended.

Chapter 7 describes practice and perspectives of psychiatrists with regard to risky procedures in psychiatry and the safety of the performance of specific

procedures by other professionals. In addition the perspectives of the management of mental health care institutions with regard to risky procedures within their organisation and the functioning of the reserved procedures regulations are presented. According to 32% of the psychiatrists there were procedures in mental health care that are not legally regulated, but are so risky that they should only be carried out by or on the orders of psychiatrists. Two thirds of the psychiatrists (66%) thought that psychotherapy should be classified as a reserved procedure. The majority of the psychiatrists (65%-96%) were of the opinion that assessment of the need for seclusion, treatment in a crisis situation and the termination of treatment can only be safely carried out by or on the orders of psychiatrists. Although 60% of the psychiatrists working in an institution had guidelines, 72% were of the opinion that these guidelines were not, or partially satisfactory. Over two thirds of the institutions (69%) thought that the reserved procedures regulations provide adequate protection for patients.

In view of these results more attention to risky procedures in the field of mental health care is recommended for legislators, management of health care institutions and the professionals associations. Especially with regard to diagnostics (indications) and therapeutic procedures.

In chapter 8, the general discussion, the strengths and limitations of the study are presented, and the research questions are addressed combining data from the different studies described in the previous chapters. In addition some concluding remarks are made about the functioning of the reserved procedures regulations, and implication of the study for practice, policy and future research are discussed. Some main point with regard to the functioning of the reserved procedures in Dutch health care will be summarised here.

This study provides empirically based insight into the functioning of the reserved procedures regulations in Dutch health care practice. The study is mainly descriptive, and because no measurements were possible before the reserved procedures regulations came into force in the Netherlands, no effect analysis with either a before-after or a control group design could be made before or after these regulations came into force. It should also be taken into account that the data were collected some 4 years ago. However, the study gives a unique, and extensive description of the conversion of the legislation in practice and the perspectives of professionals and management. The functioning of the reserved procedures regulations in Dutch health care can be considered to be moderately positive. Most professionals and management of health care institutions were of the opinion that the regulations provide sufficient protection for patients and there was no evidence for large-scale occurrence of serious dilemmas in daily practice. However, in the conversion of the regulations in daily practice, not all the requirements are strictly met. Nurses assume a very

independent and autonomous role, and mainly perform reserved procedures independently. In some cases this is a breach of the reserved procedures regulations, especially when nurses act on their own initiative without orders from a physician. However, it is a positive sign that nurses are critical of the orders given to them by physicians. The relationship between general practitioners and practice assistants is the most direct, and supervision and possibilities for intervention are, for instance, more easily arranged in general practice. Problems with and refusals of orders were not very common, but a quarter of the general practitioners did experience dilemmas with triage by practice assistants. This was mainly due to a lack of patient acceptance of the practice assistant's triage role and in some cases the educational requirements for triage were lacking.

Mental health care professionals felt a need for more regulation of the procedures, and critical attention to this aspect may also be a task for mental health care institutions. The perspectives of professionals in the all sectors was stricter for some procedures than the current regulations, presumably also resulting in a more critical review of the orders given for these procedures.
A continuous critical review of current practice and the safety of the performance of procedures that may cause harm to patients when performed by professionals with insufficient proficiency is necessary from the professionals involved, their professional associations and the management of health care institutions. When the regulations are clearly breached vigilant intervention by the management of health care institutions is needed. Improvement of the knowledge of professionals and the management of health care institutions would help to clear up existing confusion about the boundaries of authorisation. Systematic attention paid to related issues, and the creation of a safety culture in the work environment, in which professionals and management are actively involved in ensuring the safety of patients is critical in this respect. If the management of institutions fail to ensure that the care that is provided is appropriate and safe, the Health Care Inspectorate may need to be more vigilant.

Appendixes
In appendix I, an overview is given of the questions asked for the various professional groups and the management of healthcare institutions. In appendix II a list is given of the translations chosen in this thesis for specific Dutch words relating to legislation and health care.

Samenvatting

Voorbehouden handelingen in de Nederlandse gezondheidszorg: praktijk, beleid en opvattingen van artsen, verpleegkundigen en management

Dit proefschrift beschrijft een onderzoek naar de praktijk, het beleid en de opvattingen van artsen, verpleegkundigen en management van zorginstellingen ten aanzien van de uitvoering van voorbehouden en andere risicovolle handelingen in Nederlandse ziekenhuizen, thuiszorg, huisartsen praktijken en geestelijke gezondheidszorginstellingen. De vragenlijsten die de basis voor dit proefschrift vormen kwamen voort uit de evaluatie van de Wet op de beroepen in de individuele gezondheidszorg (Wet BIG).

Hoofdstuk 1 bestaat uit de inleiding, waarin de achtergrond, het doel en de vraagstellingen van het onderzoek worden gepresenteerd. In 1997 werd een nieuw systeem voor de regulering van de beroepen in de individuele gezondheidszorg geïntroduceerd, met de invoering van de Wet op de beroepen in de Individuele gezondheidszorg. Het doel van deze wet is het waarborgen en bevorderen van de kwaliteit van de beroepsuitoefening en het beschermen van patiënten in de individuele gezondheidszorg tegen ondeskundig en onzorgvuldig handelen. De keuzevrijheid van patiënten wordt in de Wet bevorderd door het opheffen van het monopolie voor artsen op het uitvoeren van medische handelingen. Om tegelijkertijd voldoende bescherming van patiënten te waarborgen werden verschillende beschermingsinstrumenten in de wet opgenomen. Dit proefschrift gaat in op één van deze instrumenten, de regeling voorbehouden handelingen.

De voorbehouden handelingen bestaan uit 11 categorieën van handelingen, waaronder heelkundige handelingen, verloskundige handelingen, katheterisaties en endoscopieën, en injecties. Voornaamste reden om handelingen op te nemen in de regeling voorbehouden handelingen is dat de uitvoering hiervan door een onvoldoende deskundig en bekwaam beroepsbeoefenaar voor patiën-

ten onacceptabele gezondheidsrisico's met zich mee zou brengen. Voorbehouden handelingen mogen alleen door beroepsbeoefenaren met een zelfstandige bevoegdheid (b.v. artsen) uit worden gevoerd, binnen hun deskundigheidsgebied. Onder bepaalde voorwaarden mogen de handelingen ook in opdracht van een zelfstandig bevoegde uit worden gevoerd door andere beroepsbeoefenaren (b.v. verpleegkundigen of doktersassistenten). Omdat aan de regeling ook strafbepalingen zijn verbonden zijn betrokken beroepsbeoefenaren strafbaar als niet aan deze voorwaarden wordt voldaan. Het hoofddoel van dit onderzoek was om een empirisch gebaseerd inzicht te krijgen in het functioneren van de regeling voorbehouden handelingen in Nederland. Het proefschrift gaat in op de volgende vraagstellingen:

1) Op welke manier is in de praktijk invulling gegeven aan de regeling voorbehouden handelingen?
2) Welke problemen worden in de dagelijkse praktijk ervaren met de regeling voorbehouden handelingen?
3) Wat zijn de opvattingen van verschillende beroepsbeoefenaren en het management van zorginstellingen over de verantwoordheid van de uitvoering van voorbehouden en andere risicovolle handelingen?

Vragenlijsten werden verstuurd naar alle respondent groepen. Om representatieve onderzoeksgroepen van beroepsbeoefenaren te kunnen includeren werden aselecte steekproeven van verpleegkundigen (n=3200), gynaecologen(n=250), internisten(n=350) en psychiaters getrokken uit het BIG register. Een aselecte steekproef van 400 huisartsen werd getrokken uit het NIVEL bestand van huisartsen. Respons onder deze groepen was respectievelijk 71%, 65%, 60%, 60% en 62%. De raden van bestuur of management van alle 117 algemene en academische ziekenhuizen, 116 thuiszorg organisaties, 44 algemeen psychiatrische ziekenhuizen en 61 RIAGG's in Nederland werden benaderd met een schriftelijke vragenlijst. Respons was respectievelijk 75%, 67%, 62% en 63%.

Hoofdstuk 2 gaat in op de kennis van artsen en verpleegkundigen in ziekenhuizen over de regeling voorbehouden handelingen, hun uitvoering van deze handelingen, de manier waarop opdrachten worden gegeven en hun opvattingen over de praktische toepasbaarheid en het functioneren van de regeling. Bijna alle respondenten wisten dat artsen bevoegd zijn om op eigen initiatief voorbehouden handelingen uit te voeren (93%-99%), en 48%-63% wist dat verpleegkundigen hiervoor niet bevoegd zijn. Een substantieel percentage van de verpleegkundigen voerden voorbehouden handelingen uit op eigen initiatief (17%-53%). Een meerderheid van de gynaecologen en internisten ging er vanuit dat het ziekenhuis de bekwaamheid van de verpleegkundigen om de voorbehouden handeling uit te voeren zouden hebben gewaarborgd (respectievelijk

58% en 65%), terwijl 82% van de verpleegkundigen de eigen bekwaamheid per handeling bepaalde. De meeste respondenten waren van mening dat de regeling voorbehouden handelingen patiënten voldoende bescherming biedt (58-72%).

In Nederlandse ziekenhuizen kan het functioneren van een gemengd systeem, waaronder de regeling voorbehouden handelingen, als gematigd positief worden gezien. Om de afstand tussen wet en praktijk te verminderen worden echter enkele aanbevelingen gedaan, zoals het accepteren van meer generieke opdrachten, als hiermee de veiligheid van patiënten niet in het gedrang komt en het hele proces van indiceren niet geheel verplaatst wordt naar het werkgebied van de verpleegkundige. Het is noodzakelijk om artsen en verpleegkundigen bewuster te maken van de huidige wetgeving wat betreft het uitvoeren van bepaalde handelingen in de dagelijkse praktijk. Omdat kennis van wetgeving gezien kan worden al eerste basis voorwaarde voor het voldoen aan deze wetgeving wordt aanbevolen om artsen en verpleegkundigen beter hierover te informeren in de opleiding of tijdens na- en bijscholingen.

Hoofdstuk 3 gaat in op het beleid dat in ziekenhuizen werd ontwikkeld naar aanleiding van de regeling voorbehouden handelingen. Daarnaast wordt ingegaan op de opvattingen van het management van ziekenhuizen ten aanzien van de regeling voorbehouden handelingen, en de mate waarin verpleegkundigen voldoen aan beschikbare richtlijnen. Alle ziekenhuizen hadden beleid ontwikkeld op het gebied van de voorbehouden handelingen. Dit is conform onze verwachtingen door de eisen in de kwaliteitswet zorginstellingen over systematische aandacht voor kwaliteit van zorg en het verlenen van verantwoorde zorg binnen de zorginstelling. Een minderheid (41%) had een toetsings- en bijstellingsbeleid ten aanzien van het omgaan met voorbehouden handelingen. De meeste ziekenhuizen ontwikkelden structurele beleidsonderdelen wat betreft de regeling voorbehouden handelingen, zoals een beleidsdocument, een beschrijving van de huidige voorbehouden handelingen of een functionaris of commissie belast met het beleid op gebied van de voorbehouden handelingen. Het is opmerkelijk dat ondanks de eisen in de kwaliteitswet zorginstellingen slechts een minderheid van de ziekenhuizen een toetsings- en bijstellingsbeleid voor de omgang met voorbehouden handelingen heeft ontwikkeld. Verdere bevordering van een dergelijk beleid is essentieel om beleid en richtlijnen geactualiseerd te houden.

Van de verpleegkundigen voldeed 61% volledig aan de instellingsrichtlijnen, 39% voldeed gedeeltelijk (2 verpleegkundigen voldeden helemaal niet). De meest genoemde reden om de richtlijnen niet te volgen was de situatie van de patiënt (75%), hoewel in noodgevallen de voorwaarden van de regeling voorbehouden handelingen niet van toepassing zijn. Van de ziekenhuizen gaf 71% aan

dat de regeling voorbehouden handelingen patiënten voldoende bescherming bied. De regeling voorbehouden handelingen lijkt in de praktijk te hebben geresulteerd in beleid in ziekenhuizen en richtlijnen voor voorbehouden handelingen. De regeling wordt als bevorderend gezien voor de kwaliteit van de zorg en de bescherming van patiënten. Desondanks worden aanbevelingen voor verbeteringen gedaan.

Hoofdstuk 4 gaat in op knelpunten die in de dagelijkse praktijk op kunnen treden als specifieke voorbehouden en niet voorbehouden handelingen worden uitgevoerd door verpleegkundigen in ziekenhuizen. Van de respondenten gaf 11-30% aan in het voorafgaande jaar problemen met dergelijke opdrachten te hebben ervaren of (overwogen) weigeringen van dergelijke opdrachten te hebben meegemaakt. Gynaecologen en internisten gaven hierbij het meest frequent aan dat de praktische uitvoering van een handeling problemen gaf (respectievelijk 44% en 30%). Het niet eens zijn met het medicatiebeleid was voor verpleegkundigen het meest genoemde probleem of reden om te overwegen een opdracht te weigeren (34% en 35%). Zowel de gynaecologen, internisten als verpleegkundigen gaven het meest frequent aan dat een opdracht werd geweigerd omdat de verpleegkundige in kwestie zelf van mening was dat zij hiervoor niet de benodigde bevoegdheid had (respectievelijk 95%, 67% en 62%).

In de praktijk ervaart slechts een minderheid van artsen en verpleegkundigen problemen bij en (overwogen) weigeringen van opdrachten voor voorbehouden en niet voorbehouden risicovolle handelingen. Het voorkomen en signaleren van problemen en (overwogen) weigeringen in de praktijk is echter voor meerdere interpretaties vatbaar. Enerzijds kan het indicatief zijn voor het voorkomen van fouten of praktische knelpunten rond de uitvoering van de handelingen. Anderzijds kan het ook gezien worden als een afspiegeling van een goed functionerend kwaliteits- en veiligheidssysteem waarin verpleegkundigen een signalerende rol hebben. Als een verpleegkundige zichzelf niet voldoende bekwaam acht om een handeling naar behoren uit te voeren moet een opdracht ook geweigerd worden. Ook een kritische en zorgvuldige overweging over het al dan niet accepteren van opdrachten is in lijn met de regeling voorbehouden handelingen. Gezien de aard en het aantal problemen en (overwogen) weigeringen geeft dit onderzoek geen aanwijzingen voor het op grote schaal voorkomen van serieuze knelpunten in de uitvoering van voorbehouden handelingen in de praktijk van Nederlandse ziekenhuizen. Het voldoende waarborgen van de kwaliteit en veiligheid van de zorg in ziekenhuizen wordt aanbevolen, onder meer door middel van richtlijnen of protocollen voor het bepalen van de bekwaamheid voor het uitvoeren van voorbehouden handelingen in de praktijk.

Hoofdstuk 5 gaat in op de praktijk met betrekking tot de regeling voorbehouden handelingen en de opvattingen van verpleegkundigen werkzaam in de thuiszorg en management van thuiszorgorganisaties. In opdracht van een arts voerden 43-71% van de verpleegkundigen minstens eenmaal per maand een intramusculaire injectie, subcutane injectie of blaaskatheterisatie uit. Van deze verpleegkundigen voerden 3 tot 13% deze handelingen in dezelfde periode ook op eigen initiatief uit, hoewel dit in strijd is met de bepalingen in de regeling voorbehouden handelingen en strafbaar is.

Van de verpleegkundigen gaf 84% aan dat er op het gebied van de voorbehouden handelingen richtlijnen aanwezig waren binnen de thuiszorg organisatie. Van hen gaf 71% aan volledig volgens deze richtlijnen te handelen. In totaal had 92% van de thuiszorg organisaties schriftelijk beleid ontwikkeld op het gebied van de regeling voorbehouden handelingen. In het voorafgaande jaar werden door 4-16% van de verpleegkundigen problemen met en (overwogen) weigeringen van opdrachten voor voorbehouden handelingen ervaren. Hoewel 42% van de thuiszorg organisaties aangaven praktische knelpunten te ervaren, gaf 80% aan dat de regeling voorbehouden handelingen patiënten voldoende bescherming bood. Gezien de aard en het aantal problemen en (overwogen) weigeringen geeft dit onderzoek geen aanwijzingen dat in de praktijk van Nederlandse thuiszorgorganisaties op grote schaal serieuze knelpunten in de uitvoering van voorbehouden handelingen voorkomen.

Hoewel wettelijke regelingen geen onnodige restricties moeten stellen als het verschuiven van taken kwaliteitsverbeterend en veilig is, is waakzaamheid geboden als delegatie te ver gaat. Instellingen moeten voldoende waarborgen stellen voor de kwaliteit en veiligheid van de zorg, zoals schriftelijke richtlijnen en protocollen waarin beschreven staat op welke manier bekwaamheid binnen de instelling bepaalt dient te worden. Met de regeling voorbehouden handelingen werd getracht meer duidelijkheid te geven over wie wat mag en werd de onafhankelijke positie van de verpleegkundige geformaliseerd. Desondanks lijkt er nog steeds sprake te zijn van verwarring over de wettelijk grenzen van deze rol. Omdat deze rol in de dagelijkse praktijk steeds onafhankelijker wordt is het beter informeren en begeleiden van verpleegkundigen aan te raden, zodat verpleegkundigen bewuster worden van de wettelijke grenzen van hun onafhankelijkheid.

Hoofdstuk 6 gaat in op de uitvoering van voorbehouden en niet voorbehouden handelingen door doktersassistenten in huisartsenpraktijken. Daarnaast wordt onderzocht welke knelpunten huisartsen ervaren en wat hun opvattingen zijn over de mate waarin het verantwoord is dat doktersassistenten bepaalde handelingen uitvoeren. Van de huisartsen gaf 93% aan de afgelopen maand minstens eenmaal een opdracht te hebben gegeven aan een doktersassistent voor

het geven van een injectie, 39% gaf aan een dergelijk opdracht te hebben gegeven voor het verrichten van een venapunctie. De meeste huisartsen (59%) bepaalden vooraf eenmaal de bekwaamheid van doktersassistenten om voorbehouden handelingen te verrichten, voordat een opdracht voor voorbehouden handelingen werd gegeven. Reden voor de meeste huisartsen om voor injecteren of het verrichten van een venapunctie een opdracht te geven aan een doktersassistent was dat de doktersassistent dit net zo goed kan als de huisarts zelf (respectievelijk 93% en 71%). Van de huisartsen werd door 8% problemen ervaren bij opdrachten aan doktersassistenten, terwijl 24% aangaf praktische problemen te ervaren met triage door doktersassistenten. In de huisartsenpraktijk worden bepaalde handelingen die traditioneel door de huisarts werden verricht nu ook door doktersassistenten verricht. Aan de voorwaarden die nodig zijn voor een veilige verschuiving van deze taken lijkt in de huisartsenpraktijk te worden voldaan: de meeste huisartsen geven opdrachten aan de doktersassistent omdat deze voldoende bekwaam is en supervisie kan in de meest gevallen ter plekke worden gegeven. Meer aandacht, bijvoorbeeld van de beroepsorganisaties van huisartsen en doktersassistenten, voor de noodzaak van continue aandacht voor en periodieke toetsing van de bekwaamheid van doktersassistenten wordt aanbevolen.

Hoofdstuk 7 beschrijft de praktijk en de opvattingen van psychiaters ten aanzien van risicovolle handelingen in de psychiatrie en de mate waarin het verantwoord is dat bepaalde handelingen door andere beroepsbeoefenaren uit worden gevoerd. Daarnaast worden de opvattingen van het management van geestelijke gezondheidszorginstellingen over risicovolle handelingen binnen hun instellingen en het functioneren van de regeling voorbehouden handelingen gepresenteerd. Volgens 32% van de psychiaters kwamen er in de geestelijke gezondheidszorg handelingen voor die niet wettelijk geregeld zijn, maar die zo risicovol zijn dat ze alleen door of in opdracht van een psychiater uit zouden mogen worden gevoerd. Twee derde van de psychiaters (66%) was van mening dat psychotherapie opgenomen zou moeten worden als voorbehouden handeling. Een meerderheid van de psychiaters (65% tot 96%) was van mening dat de inschatting van de noodzaak van separeren behandeling in een crises situatie en het beëindigen van een behandeling alleen verantwoord uitgevoerd kunnen worden door of in opdracht van een psychiater Hoewel 60% van de psychiaters die in instelling werkzaam waren aangaven dat er richtlijnen aanwezig waren op gebied van risicovolle handelingen, gaf 72% aan dat deze richtlijnen niet of slechts gedeeltelijk voldeden. Van de instellingen gaf 69% aan dat de regeling voorbehouden handelingen patiënten voldoende bescherming bied. Meer aandacht voor risicovolle handelingen in de geestelijke gezondheidszorg is aanbevolen voor de wetgever, management van gezondheidszorginstellingen

en beroepsorganisaties. Dit betreft met name diagnostische indicaties en therapeutische handelingen.
In hoofdstuk 8, de algemene discussie, worden de sterkte en zwakte punten van het onderzoek gepresenteerd en worden de vraagstellingen beantwoord met de gecombineerde resultaten van de verschillende hoofdstukken en sectoren. Aanvullend worden concluderende opmerkingen gemaakt over het functioneren van de regeling voorbehouden handelingen en implicaties van het onderzoek voor de praktijk, beleid en toekomstig onderzoek. Enkele hoofdpunten uit deze discussie zullen in deze samenvatting worden samengevat.

Het onderzoek geeft een empirisch gebaseerd inzicht in het functioneren van de regeling voorbehouden handelingen in de praktijk van de Nederlandse gezondheidszorg. Het onderzoek is grotendeels beschrijvend van aard en het was niet mogelijk om een voor- en nameting te verrichten na de inwerkingtreding van de Wet BIG. Er dient tevens rekening gehouden te worden met het feit dat de gegevens ongeveer 4 jaar voor het verschijnen van dit proefschrift werden verzameld. Daarentegen geeft het onderzoek een unieke en uitgebreide beschrijving van de manier waarop in de praktijk invulling is gegeven aan nieuwe wetgeving en de opvattingen van verschillende betrokken groepen hierop.

Het functioneren van de regeling voorbehouden handelingen kan gezien worden als gematigd positief. De meeste beroepsbeoefenaren en het management van zorginstellingen waren van mening dat de regeling voldoende bescherming bood aan patiënten en er was geen bewijs voor serieuze knelpunten in de dagelijkse praktijk met de uitvoering van de voorbehouden handelingen. Wel moet opgemerkt worden dat in de praktijk niet alle voorwaarden van de regeling na worden geleefd.

Verpleegkundigen nemen in de praktijk een bijzonder onafhankelijke en autonome positie in. In sommige gevallen is deze positie echter in strijd met de bepalingen van de regeling voorbehouden handelingen. Dit is met name het geval wanneer verpleegkundigen op eigen initiatief zonder opdracht van een arts voorbehouden handelingen uitvoeren. Het is wel positief te noemen dat verpleegkundigen zorgvuldig overwegen of zij opdrachten van artsen uit mogen voeren of niet. De relatie tussen huisartsen en doktersassistenten is het meest direct en supervisie en mogelijkheden voor interventie zijn relatief eenvoudig te realiseren. Problemen met en (overwogen) weigeringen van opdrachten kwamen niet veelvuldig voor, maar een kwart van de huisartsen gaf wel aan knelpunten te ervaren met de zeeffunctie (triage) door doktersassistenten. In de geestelijk gezondheidszorg werd door psychiaters een behoefte aangegeven aan meer regels voor het uitvoeren van bepaalde handelingen. Meer aandacht hiervoor is ook noodzakelijk vanuit geestelijke gezondheidszorg instellingen.

De opvattingen van beroepsbeoefenaren in alle sectoren waren strikter

dan de mogelijkheden in de huidige wetgeving, waarschijnlijk resulterend in een kritische beschouwing van opdrachten die voor deze handelingen worden gegeven. Een continue en kritisch beoordeling van de huidige praktijk en de veiligheid van de uitvoering van handelingen die mogelijk onacceptabele risico's voor patiënten met zich meebrengen is noodzakelijk van de betrokken beroepsbeoefenaren, beroepsorganisaties en het management van zorginstellingen. Als de regeling duidelijk overschreden worden moet ingegrepen worden door de zorginstelling. Een grotere bekendheid van de wettelijke bepalingen rond de bevoegdheden voor het uitvoeren van bepaalde handelingen is van belang onder beroepsbeoefenaren en management van zorginstellingen. Systematische aandacht voor gerelateerde aspecten en het creëren van een veiligheidscultuur in de werkomgeving, waarbij beroepsbeoefenaren en management van zorginstellingen actief betrokken zijn bij het waarborgen van de veiligheid van patiënten is hierbij van groot belang. Waar regels duidelijk overschreden worden en de veiligheid van patiënten in het geding is, is waakzaamheid van de Inspectie voor de Gezondheidszorg geboden.

In bijlage I wordt een overzicht gegeven van de vragen die in de verschillende vragenlijsten worden gesteld. In bijlage II wordt een overzicht gegeven van de vertalingen die in dit proefschrift zijn gekozen voor specifieke Nederlandse termen op gebied van wetgeving en gezondheidszorg.

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Jolanda
Amsterdam, 10 juli 2006

Curriculum Vitae

Jolanda de Bie werd geboren op 12 januari 1974, te Leiderdorp. Van 1986 tot 1992 doorliep zij het VWO op scholengemeenschap Albanianea, te Alphen aan den Rijn. In 1998 studeerde zij af in de richting Klinische Psychologie in een medische setting aan de Faculteit der Psychologie van de Universiteit van Amsterdam. Haar afstudeerstage en –onderzoek over bejegening door verpleegkundigen, verrichtte zij bij de afdeling Psychosociaal Onderzoek en Epidemiologie van het Nederlands Kankerinstituut/ Antoni van Leeuwenhoek ziekenhuis (NKI/AvL). Na haar studie deed zij onder meer onderzoek voor het NKI/AvL naar de bekendheid van en waardering over het patiënten voorlichtingscentrum.

Vanaf september 2000 was zij als sociaal wetenschappelijk onderzoeker werkzaam aan het Instituut voor Extramuraal Geneeskundig Onderzoek (EMGO), afdeling Sociale Geneeskunde, van het Vrije Universiteit Medisch Centrum. Na meegewerkt te hebben aan de landelijke evaluatie van de Wet op de beroepen in de individuele gezondheidszorg (Wet BIG) werkte zij als promovendus aan dit proefschrift over voorbehouden handelingen in de Nederlandse gezondheidszorg.

Vanaf september 2004 tot heden werkt zij als onderzoeker bij SIR Institute for Pharmacy Practice and Policy, te Leiden. Hier deed zij onder andere onderzoek naar kwaliteitsjaarplannen en kwaliteitsjaarverslagen van openbare apotheken. Voor SIR werkt zij momenteel als onderzoeker aan een project op gebied van de ontwikkeling van indicatoren voor openbare apotheken ten behoeve van toezicht door de Inspectie voor de Gezondheidszorg.

Publications of this thesis

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I

Appendix

Overview of questions (in Dutch)

Beroepsbeoefenaren*

**BB= beroepsbeoefenaren, VPK= Verpleegkundigen, INT= Internisten, GYN=Gynaecologen, HA=Huisartsen, PSY=Psychiaters*

Achtergrond gegevens

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Wat is uw geboortejaar?	19	Alle BB
Wat is uw geslacht?	Man/Vrouw	Alle BB
In welke zorgsector/ -instelling bent u momenteel werkzaam?	Algemeen ziekenhuis Academisch ziekenhuis/ Algemeen psychiatrisch ziekenhuis/ Verpleeghuis/ Verzorgingshuis/ GGD/ Gehandicaptenzorg/ Thuiszorg/ niet meer werkzaam als verpleegkundige/ anders, namelijk: (*open*)	VPK
Op welke wijze bent u momenteel als (INT/GYN) werkzaam?	Als (INT/GYN) in een academisch ziekenhuis/ als (INT/GYN) in een algemeen ziekenhuis/ Ik ben niet meer werkzaam als (INT/GYN)/ Anders, namelijk (*open*)	INT GYN
Hoeveel dagdelen per week (uitgaande van 10) bent u gemiddeld praktisch werkzaam als (*soort BB*)?	Dagdelen per week	Alle BB

Kennis van de regeling voorbehouden handelingen

Toelichting: *Onderdeel van de Wet BIG is de regeling voorbehouden handelingen. Voorbehouden handelingen zijn handelingen die buiten noodzaak (= uitgezonderd noodsituaties) alleen door daartoe bevoegden of in opdracht van hen mogen worden uitgevoerd*

Welke van de volgende beroepsbeoefenaren zijn volgens u bevoegd om buiten noodzaak op eigen initiatief (*zonder opdracht*) voorbehouden handelingen te verrichten?		
▪ Artsen ▪ Verpleegkundigen ▪ Verloskundigen ▪ Gezinsverzorgenden ▪ Verzorgenden Individuele Gezondheidszorg (VIG)	Bevoegd/ Niet-bevoegd/ Weet niet	VPK
▪ Artsen ▪ Verpleegkundigen ▪ Verzorgenden	Bevoegd/ Niet-bevoegd/ Weet niet	INT GYN
▪ Artsen ▪ Verpleegkundigen ▪ Verzorgenden ▪ Gezondheidszorgpsychologen ▪ Maatschappelijk werkers	Bevoegd/ Niet-bevoegd/ Weet niet	PSY

Onderdelen	*Antwoord mogelijkheden*	*Groep*
In hoeverre zijn de volgende onderdelen van de regeling voorbehouden handelingen voor u (voldoende) duidelijk of onduidelijk?	▪ Welke handelingen voorbehouden zijn aan artsen ▪ Welke handelingen zonder toezicht en tussenkomst door een verpleegkundige mogen worden uitgevoerd ▪ De manier waarop een opdracht gegeven dient te worden gegeven ▪ De voorwaarden voor het aannemen van een opdracht ▪ De manier waarop bekwaamheid dient te worden bepaalt ▪ De manier waarop aanwijzingen dienen te worden gegeven ▪ De manier waarop toezicht en tussenkomst dienen te worden geboden ▪ De verdeling van verantwoordelijkheid bij het geven en aannemen van opdrachten ▪ Anders, namelijk: (*open*)	VPK INT GYN
Uitvoeren van voorbehouden handelingen, opdrachten en bekwaamheid		
Hoe vaak per maand krijgt u naar schatting <u>opdrachten van een arts</u> om de volgende handelingen te verrichten en hoe vaak verricht u deze handelingen op <u>eigen initiatief</u> (zonder opdracht)? *Wij verzoeken u het schema volledig in te vullen. Als u de genoemde handelingen niet verricht kunt u nul (0) invullen.*	Verricht in opdracht van arts; aantal keren per maand Verricht op eigen initiatief; aantal keren per maand ▪ Blaaskathetherisatie ▪ Inbrengen perifeer infuus ▪ Subcutaan injecteren ▪ Intramusculair injecteren ▪ Intraveneus injecteren (rechtstreeks)	VPK
Hoe vaak verricht u naar schatting per maand de volgende handelingen <u>*zelf*</u> en hoe vaak geeft u per maand opdrachten voor deze handelingen aan een <u>*verpleegkundige*</u> ? *Wij verzoeken u het schema volledig in te vullen. Als u de genoemde handelingen niet verricht kunt u nul (0) invullen.*	Zelf verricht ; aantal keren per maand / Opdracht aan een verpleegkundige; aantal keren per maand ▪ Blaaskathetherisatie ▪ Inbrengen perifeer infuus ▪ Subcutaan injecteren ▪ Intramusculair injecteren ▪ Intraveneus injecteren (rechtstreeks)	INT GYN
Hoe vaak verricht u naar schatting per maand de volgende handelingen <u>*zelf*</u> en hoe vaak geeft u per maand opdrachten voor deze handelingen aan de <u>*doktersassistent*</u> ? *Wij verzoeken u het schema volledig in te vullen. Als u de genoemde handelingen niet verricht kunt u nul (0) invullen.*	Zelf verricht ; aantal keren per maand Opdracht aan de doktersassistent aantal keren per maand ▪ Injecteren ▪ Venapunctie ▪ Hechten	HA

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Op welke wijze bepaalt u <u>*uw eigen bekwaamheid*</u> als u een opdracht van een arts krijgt om een voorbehouden handeling te verrichten? *meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ Niet van toepassing, ik krijg nooit een dergelijke opdracht ▪ Dit laat ik aan de verantwoordelijkheid van de leidinggevende over ▪ Ik veronderstel mijn bekwaamheid op grond van de door mij gevolgde opleiding ▪ Ik bepaal periodiek(bijv. eens per jaar) voor welke handelingen ik bekwaam ben (evt. In overleg met mijn leidinggevende) ▪ Ik beoordeel per patiënt of ik bekwaam ben om de handeling te verrichten ▪ Ik beoordeel per handeling of ik bekwaam ben om de handelingen te verrichten ▪ Ik heb een bekwaamheidsverklaring voor een of meerdere voorbehouden handelingen ▪ Ik bepaal aan de hand van een protocol of ik bekwaam ben ▪ Anders, namelijk: (*open*)	VPK
Op welke wijze bepaalt u de <u>*bekwaamheid van een verpleegkundige*</u> aan wie u een opdracht tot een voorbehouden handeling geeft? *meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ Niet van toepassing, ik geef nooit een dergelijke opdracht ▪ Dit laat ik aan de verantwoordelijkheid van de beroepsbeoefenaar over ▪ Ik veronderstel de bekwaamheid van de beroepsbeoefenaar op grond van de gevolgde opleiding ▪ Ik beoordeel per patiënt of de beroepsbeoefenaar bekwaam is om de handeling te verrichten ▪ Ik beoordeel per handeling of de beroepsbeoefenaar bekwaam is om de handelingen te verrichten ▪ Ik ga ervan uit dat de instelling waar ik werk heeft gewaarborgd dat de verpleegkundigen bekwaam zijn ▪ Anders, namelijk: (*open*)	INT GYN
Op welke wijze bepaalt u de <u>*bekwaamheid van een doktersassistent*</u> aan wie u een opdracht tot een voorbehouden handeling geeft? *meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ Niet van toepassing, ik geef nooit een dergelijke opdracht ▪ Dit laat ik aan de verantwoordelijkheid van de beroepsbeoefenaar over ▪ Ik veronderstel de bekwaamheid van de beroepsbeoefenaar op grond van de gevolgde opleiding ▪ Ik stel vooraf eenmaal vast voor welke handelingen de beroepsbeoefenaren met wie ik werk bekwaam zijn ▪ Ik bepaal periodiek (bijv. eens per jaar) voor welke handelingen de beroepsbeoefenaren met wie ik samenwerk bekwaam zijn ▪ Ik beoordeel per patiënt of de beroepsbeoefenaar bekwaam is om de handeling te verrichten ▪ Ik beoordeel per handeling of der beroepsbeoefenaar bekwaam is om de handelingen te verrichten ▪ Anders, namelijk: (*open*)	HA

Onderdelen	*Antwoord mogelijkheden*	*Groep*
In hoeverre gelden voor u de volgende redenen om een verpleegkundige (*HA: de doktersassistent*) een opdracht te geven tot (*zie antwoord mogelijkheden voor gevraagde handelingen*)?	Voor injecteren i.v. en blaaskatheterisatie (vrouw): Ja/ Nee Voor injecteren en Venapuntie: Ja/ Nee	INT GYN HA
Hoe vaak krijgt** u op de volgende wijze een opdracht tot (zie antwoordmogelijkheden voor gevraagde handelingen)? *Als u in de afgelopen 12 maanden geen opdrachten heeft gekregen voor de handelingen kunt u verder gaan met vraag >> (skip naar volgende cluster vragen)*	altijd/meestal/soms/nooit Voor injecteren i.v. en blaaskatherisatie (vrouw): altijd meestal/soms/nooit Wijze van opdracht geven: ▪ Schriftelijk ▪ Mondeling, zonder schriftelijke bevestiging ▪ Mondeling waarna schriftelijke bevestiging Anders, namelijk: (*open*) *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen of doktersassistenten)*	VPK INT GYN
Hoe vaak krijgt** u de volgende soorten opdrachten tot (*zie antwoordmogelijkheden voor gevraagde handelingen*)? *Als u in de afgelopen 12 maanden geen opdrachten heeft gekregen voor de handelingen kunt u verder gaan met vraag >> (skip naar volgende cluster vragen)*	Voor injecteren i.m. en blaaskatheterisatie (vrouw):Meestal/ Soms/ Zelden/ Nooit Voor injecteren i.v. en blaaskatherisatie (vrouw): Meestal/ Soms/ Zelden/ Nooit Soorten opdrachten: ▪ 'Zo-nodig' of 'als-dan' opdracht ▪ Eén opdracht voor meerdere keren ▪ Anders, namelijk: (*open*) *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen)*	VPK INT GYN
Hoe vaak krijgt** u de volgende aanwijzingen , indien u een opdracht krijgt tot (*zie antwoordmogelijkheden voor gevraagde handelingen*)?	Voor injecteren i.m. en blaaskatheterisatie (vrouw): altijd/meestal/soms/nooit Voor injecteren i.v. en blaaskatherisatie (vrouw): altijd meestal/soms/nooit Aanwijzingen over: ▪ De handelswijze in het algemeen ▪ De handelswijze bij deze patiënt ▪ De eventuele complicaties en bijwerkingen Anders, namelijk: (*open*) *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen)*	VPK INT GYN

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Hoe vaak worden de volgende mogelijkheden voor toezicht en tussenkomst geboden,indien u een opdracht krijgt**tot het intramusculair injecteren en/of het katheteriseren van de blaas? *Als u in de afgelopen 12 maanden geen opdrachten heeft gekregen voor de handelingen kunt u verder gaan met vraag >> (skip naar volgende cluster vragen)*	Voor injecteren i.m. en blaaskatheterisatie (vrouw): altijd/meestal/soms/nooit Voor injecteren i.v. en blaaskatherisatie (vrouw): altijd meestal/soms/nooit Voor injecteren en venapunctie: altijd/meestal/soms/nooit ▪ Direct toezicht op de plaats van de handeling ▪ Fysiek in kunnen grijpen als er iets mis gaat ▪ Op afstand bereikbaar zijn ▪ Controle achteraf Anders, namelijk: (*open*) *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen of doktersassistenten)*	VPK INT GYN HA
Hoe vaak krijgt u een opdracht overgedragen via een leidinggevende of een andere verpleegkundige en hoe vaak krijgt u een opdracht via een protocol?	Voor injecteren i.m. en blaaskatheterisatie (vrouw): meestal/soms/zelden/nooit ▪ Overgedragen opdracht via leidinggevende ▪ Overgedragen opdracht via andere verpleegkundige ▪ Opdracht via protocol	VPK
Opvattingen over verantwoordheid uitvoering handelingen		
In hoeverre is het volgens u verantwoord om de volgende handelingen te laten verrichten door (*zie antwoordmogelijkheden voor beroep waar dit voor werd gevraagd*)?	1) Niet verantwoord, alleen door de arts te verrichten/ 2) Verantwoord, mits in opdracht van een arts, volgens de regeling voorbehouden handelingen/ 3) Verantwoord, als bij 2), maar bieden van toezicht en tussenkomst geen vereiste/ 4) verantwoord, géén opdracht van een arts nodig	
	Gevraagd over verrichtten door verpleegkundige ▪ Venapunctie ▪ Inbrengen perifeer infuus ▪ Intraveneus injecteren (rechtstreeks) ▪ Geneesmiddelen toedienen via infuus (fles/zak) ▪ Bedienen spuitpomp ▪ Intramusculair injecteren ▪ Inbrengen maagsonde ▪ Hechten ▪ Blaaskatheterisatie man ▪ Blaaskatheterisatie vrouw ▪ Verwijderen epiduraal katheter ▪ Beoordelen ECG ▪ Beoordelen sedativa	VPK

Onderdelen	*Antwoord mogelijkheden*	*Groep*
In hoeverre is het volgens u verantwoord om de volgende handelingen te laten verrichten door (*zie antwoordmogelijkheden voor beroep waar dit voor werd gevraagd*)?	1) Niet verantwoord, alleen door de arts te verrichten/ 2) Verantwoord, mits in opdracht van een arts, volgens de regeling voorbehouden handelingen/ 3) Verantwoord, als bij 2), maar bieden van toezicht en tussenkomst geen vereiste/ 4) verantwoord, géén opdracht van een arts nodig	
	Gevraagd over verrichten door verpleegkundige ▪ Venapunctie ▪ Inbrengen perifeer infuus ▪ Intraveneus injecteren (rechtstreeks) ▪ Geneesmiddelen toedienen via infuus (fles/zak) ▪ Bedienen spuitpomp ▪ Inbrengen maagsonde ▪ Blaaskatheterisatie man ▪ Blaaskatheterisatie vrouw	GYN INT
	Gevraagd over verrichten door een gemiddeld bekwaam en ervaren doktersassistent ▪ Vaccineren ▪ Hechten ▪ Venapunctie ▪ Spirometrie ▪ Wondtoilet ▪ Cervixuitstrijkje maken ▪ Spiraal plaatsen ▪ Beoordelen noodzaak consult ▪ Wratten aanstippen ▪ Allergietest afnemen ▪ Desensibiliseren	HA
	Gevraagd over verrichten door: gezondheidszorgpsycholoog/ sociaal psychiatrisch verpleegkundige/ maatschappelijk werker ▪ Beoordelen noodzaak behandeling in crisissituatie ▪ Beoordelen noodzaak consult psychiater in noodsituatie ▪ Beoordelen separatie patiënt ▪ Beoordelen beëindiging behandeling ▪ Intake gesprek ▪ Individuele psychotherapie ▪ Groepstherapie	PSY
Ervaart u in de praktijk knelpunten ten aanzien van de vervulling van de ‘ zeeffunctie' door de doktersassistent?	Ja/Nee s.v.p kort toelichten: (*open*)	HA

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Komen er volgens u in de GGZ handelingen voor die zo risicovol zijn dat zij uitsluitend door psychiaters of in opdracht van hen zouden mogen worden verricht?	Ja/ Nee/ Weet niet	PSY
Welke handelingen zijn dit (*zie vorige vraag*) volgens u en zijn voor deze handelingen extra regelingen nodig?	Handeling 1/2/3: (*open*); Nee, geen extra regeling nodig/ Ja, via instellingsprotocol/ Ja, via regeling voorbehouden handelingen s.v.p. kort toelichten (*open*)	PSY
Is het volgens u verantwoord wanneer ook een psychotherapeut (niet zijnde een psychiater) en/of een gezondheidszorgpsycholoog de door u genoemde handelingen (1/2/3) op eigen initiatief (zonder opdracht) zou mogen verrichten?	Handeling 1/2/3 (zie vorige vraag); alleen verantwoord door psychotherapeut/ alleen verantwoord door gezondheidszorgpsycholoog/ verantwoord door beiden/ nee, niet verantwoord	PSY
Zou psychotherapie aangemerkt moeten worden als voorbehouden handeling?	Ja/Nee/Weet niet s.v.p, kort toelichten: (*open*)	PSY
Voorbehouden handelingen: problemen en (overwogen) weigeringen		
Is er de afgelopen 1 2 maanden wel eens een probleem opgetreden wanneer u een opdracht kreeg** van een arts of een andere beroepsbeoefenaar om een van de in vraag (*vraag verantwoordheid*) genoemde handelingen te verrichten?	Ja, namelijk Maal/ Nee, nooit een probleem opgetreden (>> *skip naar volgende vraag)/* Nee, nooit opdracht gekregen** (>> *skip naar volgende cluster vragen)* *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen of doktersassistenten)*	VPK INT GYN HA
Kunt u ten aanzien van de laatste keer dat er een probleem optrad bij het krijgen van een dergelijke opdracht aangeven welke soort beroepsbeoefenaar de opdracht gaf**, welke handeling het betrof en welk probleem optrad?	Beroepsbeoefenaar die de opdracht gaf**: (*open*)/ Handeling waarvoor opdracht werd gegeven: (*open*)/ Opgetreden probleem: (*open*) *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen of doktersassistenten)*	VPK INT GYN HA
Is het de afgelopen 1 2 maanden wel eens voorgekomen dat u een opdracht van een arts of een andere beroepsbeoefenaar tot een in de vraag (*vraag verantwoordheid*) genoemde handelingen heeft geweigerd uit te voeren?	Ja, namelijk Maal/ Nee, nooit een opdracht geweigerd *(>> skip naar volgende vraag)* *(** voor de relevante vragenlijsten voor de artsen werd hier gevraagd naar gegeven opdrachten aan verpleegkundigen of doktersassistenten)*	VPK INT GYN HA

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Kunt u ten aanzien van de laatste keer dat u een opdracht van een arts of een andere beroepsbeoefenaar weigerde tot het verrichten van een dergelijke handeling, aangeven welke soort beroepsbeoefenaar de opdracht gaf? Ook vragen wij u in te vullen welke handeling het betrof, wat de reden van de weigering was en hoe u heeft gehandeld na de weigering.	Beroepsbeoefenaar die de opdracht gaf**: (*open*)/ Handeling waarvoor opdracht werd gegeven: (*open*)/ Reden om de opdracht te weigeren: (*open*)/ Handelswijze na de weigering: (*open*)	VPK INT GYN HA
Is het de afgelopen 1 2 maanden wel eens voorgekomen dat u een opdracht van een arts of een andere beroepsbeoefenaar tot een in de vraag (*vraag verantwoordheid*) genoemde handelingen overwoog te weigeren?	Ja, namelijk Maal/ Nee, nooit een opdracht overwogen te weigeren (>> *skip naar volgende vraag)*	VPK
Kunt u ten aanzien van de laatste keer dat u overwoog een opdracht van een arts of een andere beroepsbeoefenaar tot het verrichten van een dergelijke handeling te weigeren, aangeven welke soort beroepsbeoefenaar de opdracht gaf? Ook vragen wij u in te vullen welke handeling het betrof, wat de reden was dat u overwoog de opdracht te weigeren en hoe u uiteindelijk heeft gehandeld.	Beroepsbeoefenaar die de opdracht gaf: (*open*)/ Handeling waarvoor opdracht werd gegeven: (*open*)/ Reden om te overwegen de opdracht te weigeren: (*open*)/ Uw uiteindelijke handelswijze: (*open*)	VPK
Voorbehouden handelingen – richtlijnen/protocollen		
Bestaan er in uw instelling of op uw afdeling schriftelijke richtlijnen/ protocollen ten aanzien van voorbehouden handelingen***? ****(voor psychiaters werd gevraagd naar de handelingen genoemd bij verantwoordheid handelingen)*	Ja/ Nee (>> *skip naar volgende cluster vragen*) Ja in soort instelling (*open*)/ Nee/ Niet van toepasing, niet werkzaam in een instelling	VPK PSY
Voldoen deze richtlijnen/protocollen?	Ja, volledig/ ten dele/ nee s.v.p. kort toelichten (*open*)	PSY

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Welke van de volgende onderdelen worden beschreven in deze richtlijnen/protocollen? *Meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ De handelingen die zijn voorbehouden aan artsen ▪ De handelingen die zonder toezicht en tussenkomst door een verpleegkundige mogen worden uitgevoerd ▪ De manier waarop een opdracht dient te worden gegeven ▪ De voorwaarden voor het aannemen van een opdracht ▪ De manier waarop bekwaamheid dient te worden bepaald ▪ De manier waarop aanwijzingen dienen te worden gegeven ▪ De manier waarop toezicht en tussen komst dienen te worden geboden ▪ De verdeling van verantwoordelijkheid bij het geven en het aannemen van opdrachten ▪ Anders, namelijk: (*open*)	VPK
Handelt u bij het verrichten van voorbehouden handelingen volgens deze richtlijnen/protocollen?	Ja volledig (>> *skip naar volgende cluster vragen*)/ Ten dele/ Nee	VPK
Wat zijn voor u redenen om van deze richtlijnen/protocollen af te wijken? *Meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ De richtlijnen/protocollen zijn niet helder geformuleerd ▪ De richtlijnen/protocollen zijn niet praktisch genoeg ▪ Ik ben niet (volledig) op de hoogte van de inhoud van deze richtlijnen/protocollen ▪ De situatie van de patient ▪ Tijdsgebrek ▪ Anders, namelijk: (*open*)	VPK
Voorbehouden handelingen: opvattingen		
In hoeverre bent u het met de volgende beweringen over de Wet BIG eens of oneens?	Helemaal mee eens/ meer eens dan oneens/ noch eens, noch oneens/ meer oneens dan eens/ helemaal mee oneens ▪ De regeling voorbehouden handelingen legt mij teveel beperkingen op ▪ Patiënten zijn voldoende beschermd door de regeling voorbehouden handelingen ▪ De regeling voorbehouden handelingen is een verbetering ten opzichte van eerdere regelgeving op dit gebied ▪ In mijn werk merk ik geen verandering door de regeling voorbehouden handelingen ▪ De regeling voorbehouden handelingen sluit goed aan op de praktijk ▪ De lijst van voorbehouden handelingen is voor mijn werksituatie toereikend	VPK INT GYN HA PSY

Onderdelen	*Antwoord mogelijkheden*	*Groep*
Zijn de voorwaarden die in de regeling voorbehouden handelingen in de Wet BIG worden gesteld aan het geven en aannemen van opdrachten volgens u in de praktijk uitvoerbaar?	Ja, helemaal/ Ja, enigszins/ Nee/ Weet niet	VPK INT GYN HA

Zorginstellingen (raad van bestuur /management)*

Toelichting: *Onderdeel van de Wet BIG is de regeling voorbehouden handelingen. Voorbehouden handelingen zijn handelingen die buiten noodzaak alleen door daartoe bevoegden of in opdracht van hen mogen worden uitgevoerd*

Onderdelen	*Antwoord mogelijkheden*	
Op welke wijze is in uw instelling het beleid ten aanzien van voorbehouden handelingen uitgewerkt? *Meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	▪ Niet van toepassing, geen beleid uitgewerkt ten aanzien van voorbehouden handelingen *(>> skip naar volgende cluster vragen)* ▪ Een beleidsnotitie ten aanzien van voorbehouden handelingen ▪ Een beschrijving van de in de instelling voorkomende voorbehouden handelingen ▪ Een functionaris/commissie die zorg draagt voor het beleid rond voorbehouden handelingen ▪ Training- en scholingsbeleid voor beroepsbeoefenaren voor het verrichten van voorbehouden handelingen ▪ Protocollen/richtlijnen voor bepaalde voorbehouden handelingen ▪ Protocollen/richtlijnen voor alle voorbehouden handelingen ▪ Bekwaamheidsverklaringen voor individuele beroepsbeoefenaren voor het verrichten van voorbehouden handelingen ▪ Bekwaamheidsverklaringen voor groepen beroepsbeoefenaren voor het verrichten van voorbehouden handelingen ▪ Schriftelijke toetsings- en bijstellingsbeleid t.a.v. het omgaan met voorbehouden handelingen ▪ Ander, nl (*open*)	ZH TZ
Komen er in uw instelling handelingen voor die niet onder de regeling voorbehouden handelingen vallen, maar die zo risicovol zijn dat zij uitsluitend door artsen of in opdracht van hen zouden mogen worden verricht?	Ja/ Nee/Weet niet *(>> skip naar volgende cluster vragen)*	GGZ

Onderdelen	*Antwoord mogelijkheden*	
Welke handelingen zijn dit volgens u en zijn voor deze handelingen extra regelingen (via een instellingsprotocol of via de regeling voorbehouden handelingen in de Wet BIG) nodig	Per handeling (1-3) (*open*) Nee, geen extra regeling nodig/ Ja, via instellingsprotocol, Ja, via regeling voorbehouden handelingen s.v.p. kort toelichten (*open*)	GGZ
Hoe wordt op dit moment in uw instelling omgegaan met deze handelingen? *Meerdere antwoorden mogelijk, antwoord mogelijkheden aan te kruisen*	Hiermee wordt omgegaan alsof zijn voorbehouden handelingen zijn/ Hiervoor zijn protocollen/richtlijnen opgesteld/ Hiervoor zijn geen extra maatregelen getroffen/ anders, namelijk (*open*)	GGZ
Is er in uw instelling behoefte aan vermindering van het aantal handelingen dat onder de regeling voorbehouden handelingen?	Ja, namelijk voor: (*open*) / Nee	ZH TZ GGZ
Is er in uw instelling behoefte aan uitbreiding van het aantal handelingen die verpleegkundigen functioneel zelfstandig (=zonder toezicht en tussenkomst) mogen verrichten?	Ja, namelijk voor: (*open*)/ Nee	ZH
Worden er in uw instelling bepaalde knelpunten ervaren ten aanzien van de regeling voorbehouden handelingen die in dit onderdeel van de vragenlijst niet aan de orde zijn gekomen?	Ja/ Nee s.v.p. kort toelichten (*open*)	ZH
Wordt in uw instelling de regeling voorbehouden handelingen ervaren als een instrument dat patiënten voldoende bescherming biedt?	Ja/Nee/Weet niet	ZH TZ GGZ

II

Appendix

Translations used in this thesis

In this appendix an overview is given of the translations used in this thesis for some specific Dutch words, referring to legislations, regulations or health care. When available, the translations provided by the Dutch Ministry of Health, Welfare and Sports were used.

Termen gerelateerd aan de Wet op de beroepen in de individuele gezondheidszorg	
▪ De Wet op de beroepen in de individuele gezondheidszorg (Wet BIG)	The Individual Health Care Professions Act (IHCP Act)
▪ Regeling voorbehouden handelingen	Reserved procedures regulations
▪ Functionele zelfstandigheid (een functioneel zelfstandige status)	Functional independence (a functional independent status)
▪ Deskundigheidsgebied	Field of expertise
▪ Bevoegdheid	Authorisation
▪ Zelfstandige bevoegdheid	Direct authorisation
▪ Bekwaamheid	Proficiency
▪ Deskundigheid	Competence
▪ In opdracht van	On the orders of
▪ Op eigen initiatief (zonder opdracht)	On their own initiative (without orders)
▪ Aanwijzingen	Instructions
▪ Regeling van supervisie en de mogelijkheid van tussenkomst	Arrangement for supervision and the possibility of intervention
▪ Tuchtrecht	Disciplinary code
▪ Het register voor beroepen in de individuele gezondheidszorg (BIG register)	The register of individual health care professionals (IHCP register)

Termen gerelateerd aan overige wet- of regelgeving	
▪ Kwaliteitswet Zorginstellingen (KZI)	Health Care Institutions Quality Act (CIQ Act)
▪ Verantwoorde zorg	Appropriate care
▪ Wet bijzondere opnemingen psychiatrische ziekenhuizen (BOPZ)	The Psychiatric Hospitals Compulsory Admission Act
▪ Wet op de geneesmiddelen voorziening (WOG)	The supply of Medicines Act

Overige termen	
▪ Inspectie voor de Gezondheidszorg	Health Care Inspectorate
▪ Algemeen Psychiatrische ziekenhuizen	General Psychiatric hospitals
▪ Regionale instellingen voor ambulante geestelijke gezondheidszorg (RIAGG)	Regional institutions for ambulatory mental health care
▪ Doktersassistent	Practice assistant